EPA Jacket 5481-219 Vol.1

| Det & | Acti CODE. | APPL BATE |
|-------|----------------------------------|-----------|
| 1 | 435 605 DE REGISTRATION | 8/18/81 |
| 2 | 600 658 RE DEG | 11/6/81 |
| 3 | 450 Protocol | 10/28/82 |
| 4 | 450 Mutagenicity protocol review | 4/12/84 |
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| | | 3 |

New meeting request from Dabble Edwards

Begins:

03/23/2004 11:00 AM Lacal Time 03/23/2004 12:00 PM Lovel This

Ends: Title!

Pre-Brief for Old Chemicals (NAA)

Location:

650

Chair: Sent by: Debbie Edwarde/DC/USEPA/US Linda Murray/DC/USEPA/US

To (required): Abdallah Khasawinah/DC/USEPA/US@EPA, Alan Halvorson/DC/USEPA/US@EPA, Allan

Vaughan/DC/USEPA/US@EPA, Betty Shackleford/DC/USEPA/US@EPA, Bill

Diarrond/DC/USEPA/US@EPA, Carol Stangel/DC/USEPA/US@EPA, Clmino.Pat@EPA.GOV@EPA,

Cynthia Giles-Parker/DC/USEPA/US@EPA, David Hrdy/DC/USEPA/US@EPA, Elizabeth

Leovey/DC/USEPA/US@EPA, Gary Otakia/DC/USEPA/US@EPA, Qagraa Harndon/DC/USEPA/US@EPA

James Falkel/DC/USEPA/US@EPA, John Bezuin/DC/USEPA/US@EPA, John

Lenhy/DC/USEPA/US@EPA, Jose Melendez/DC/USEPA/US@EPA, Kimberly Nesci/DC/USEPA/US@EPA, Linda Murray/DC/USEPA/US@EPA, Linda Propat/DC/USEPA/US@EPA, Lois RossI/DC/USEPA/US@EPA.

Mah Shamim/DC/USEPA/US@EPA, Margeret Rice/DC/USEPA/US@EPA, Mark Hartman/DC/USEPA/US@EPA, MarkT Howard/DC/USEPA/US@EPA, Michael

Goodis/DC/USEPA/US@EPA, Moknir Mezur/DC/USEPA/US@EPA, Nell Anderson/DC/USEPA/US@EPA, Nicole Zinn/DC/USEPA/US@EPA, Peter Caulkins/DC/USEPA/US@EPA, Ray Kent/DC/USEPA/US@EPA.

Rebecca Daise/DC/USEPA/US@EPA, Richard Dumas/DC/USEPA/US@EPA, Robert

Nicnaliv/DC/USEPA/US@EPA, Steve Jarboe/DC/USEPA/US@EPA, Steve Knizner/DC/USEPA/US@EPA.

Steven Bradbury/DC/USEPA/US@EPA, Susan Lewis/DC/USEPA/US@EPA, Teniettiv

Leighton/DC/USEPA/US@EPA, Tine Levine/DC/USEPA/US@EPA, William Jordan CAISEPA/US@EPA

cc (optional):

Starting: 03/23/2004 Applies to: This instance only

Description

Nanthalens Acetic Acid will be the subject of Thursday's, March 25th Old Chemicals Briefing for Jim Jesse...

has delegated this meeting request to you

Beginst

03/23/2604 11:00 Alli Local Thire

Ends:

02/23/2004 12:00 MA Lucal Nine

Title:

Pre-Brief for Old Chemicals (NAA):

Locations

Chair:

Debble Edwards/DC/USEPA/US

To (required): Abdallah Khasawinah/DC/USEPA/US@EPA, Alan Halvorson/DC/USEPA/US@EPA, Allan

Veughan/DC/USEPA/US@EPA, Betty Shackleford/DC/USEPA/US@EPA, BIII

Diamond/DC/USEPA/US@EPA, Carol Stangel/DC/USEPA/US@EPA, Cimino.Pat@EPA.GOV@EPA,

Cynthie Oiles-Parker/DC/USEPA/US@EPA, David Hrdy/DC/USEPA/US@EPA, Elizabeth

Leovay/DC/USEPA/US@EPA, Gary Otakia/DC/USEPA/US@EPA, George Herndon/DC/USEPA/US@EPA

James Felkel/DC/USEPA/US@EPA, John Bezuin/DC/USEPA/US@EPA, John

Leahy/DC/USEPA/US@EPA, Jose Melendez/DC/USEPA/US@EPA, Kimberly Nescl/DC/USEPA/US@EPA, Linda Murray/DC/USEPA/US@EPA, Linda Propet/DC/USEPA/US@EPA, Lois Rossi/DC/USEPA/US@EPA, J

Mah Shamim/DC/USEPA/US@EPA, Mergeret Rice/DC/USEPA/US@EPA, Mark Hartman/DC/USEPA/US@EPA, MarkT Howard/DC/USEPA/US@EPA, Michael

Goodis/DC/USEPA/US@EPA, Mojmir Mazur/DC/USEPA/US@EPA, Nell Anderson/DC/USEPA/US@EPA. Nicole Zinn/DC/USEPA/US@EPA, Pater Caulkins/DC/USEPA/US@EPA, Ray Kent/DC/USEPA/US@EPA,

Rebacca Daiss/DC/USEPA/US@EPA, Richard Dumas/DC/USEPA/US@EPA, Robert

Mcnały/DC/USEPA/US@EPA, Steve Jarboa/DC/USEPA/US@EPA, Steve Kniznar/DC/USEPA/US@EPA,

Steven Bradbury/DC/USEPA/US@EPA, Susan Lewb/DC/USEPA/US@EPA, Timothy

Leighton/DC/USEPA/US@EPA, Tins Levine/DC/USEPA/US@EPA, William Jordan/DC/USEPA/US@EPA

cc (optional);

03/23/2004 Starting:

Applies to: This historica only

Description

Manthelene Acetic Acid will be the subject of Thursday's, March 25th

Old Chemicals Briofing for Jim Jones ...

Nets meeting request from MarkT Howard

Begins:

03/17/2004-09:00 AM Local Time:

Enda:

02/17/2004 10:00 AM Local Year

Title:

NAA Team Meeting

Location:

Conference Room 650/DC-Crystel Mail #2-OPP

Chair:

MarkT Howard/DC/USEPA/US

To (required): Abdellsh Khesawinsh/DC/USEPA/US@EPA, Alan Halvorson/DC/USEPA/US@EPA, Allan

Vaughan/DC/USEPA/US, David Hrdy/DC/USEPA/US@EPA, Gary Otakie/DC/USEPA/US@EPA, James Felkel/DC/USEPA/US@EPA, John Bazuin/DC/USEPA/US@EPA, Jose Melendez/DC/USEPA/US@EPA,

Kimberly Nesci/DC/USEPA/US, Mah Shamim/DC/USEPA/US@EPA, Michael

Goodle/DC/USEPA/US@EPA, Mojmir Mazur/DC/USEPA/US@EPA, Nicole Zinn/DC/USEPA/US@EPA,

Ray Kent/DC/USEPA/US@EPA, Rebecce Daiss/DC/USEPA/US@EPA, Stave-

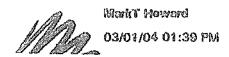
Jarboe/DC/USEPA/US@EPA, Timothy Leighton/DC/USEPA/US@EPA

sc (optional);

Neil Anderson/DC/USEPA/US

Description

This meeting is to prepare for the Old Chemicals Briefing with Jim Jones on March 25th. We will have a brief discussion of the RED and comments from the registrant if time allows.



To: John Bazuin/DC/USEPA/US@EPA
cc: Neil Anderson/DC/USEPA/US

Subject: Re: NAA 🖺

John,

Thanks for the RD update on NAA. I'm going to put Cynthia on the list as the PM and the branch chief for the case.

I'll send her a copy of the heads up. Invitations to the Old Chemicals meeting and pre-meeting should be coming from Pineapple soon.

I have to complete the first full draft of the NAA RED by the end of this month. However, given the need to look sharp at the Old Chemicals meeting, you should plan on having your completed history of NAA and its associated salts by Friday March 12th so that information can be incorporated into the Old Chemicals briefing paper. The briefing paper's first draft will be given to the team at the NAA team meeting the week of March 15th. Dress rehearsal for Old Chemicals is on Tuesday March 23rd.

Mark

John Bazuin

John Bazuin 03/01/04 01:13 PM

To: MarkT Howard/DC/USEPA/US@EPA

cc:

Subject: Re: NAA 🗎

Mark,

I'm still the line guy for NAA & Salts and Cynthia Giles-Parker is still the PM for this case. As to who the Branch Chief is, that depends on what week it is! By that I mean that the two PMs in Fungicide branch, Cynthia and Mary Weller, are flip-flopping as Branch Chief, each one taking a two-week stint before handing the job off to the other one for two weeks. I don't know how long this will go on. I think Mary Weller may have just started a two-week BC stint but I'm not totally sure.

I'll have to bone up on NAA & Salts again. I have not had to do much with it in the past while. I'm supposed to be writing the regulatory history chapter for the RED and have done a little along that line, but have been too swamped to pursue it very hard.

Were you planning to schedule that meeting on the Notes calendar?

<<<<0>>>>

MarkT Howard

MarkT Howard 03/01/04 09:55 AM To: John Bozuin/DC/USEPA/US@EPA

cc: doct: N

Subloct: NAA

.fofte.

I sent you an invitation to the Old Chemicals Meeting and pre-meeting. (I am the CRM, who replaced Tyler Lane on NAA). I don't know who is the current (or acting?) branch chief is. I'd appraciate any updates on who in RD is working on NAA.

Thanks, Mark



John Bazuin 03/01/04 01:03 PM

To: MerkT Howard/DC/USEPA/US

CC

cc: John Bazuln/DC/USEPA/US@EPA

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<<<<0>>>>

MarkT Howard

MarkT Howard

To: John Bezuin/OC/USEPA/US@EPA

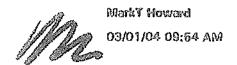
03/01/04 09:55 AM

cc: Subject: NAA

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Thanks, Mark



To: Rebocco Doise/DC/USEPA/US@EPA, Allen Vaughen/DC/USEPA/US, John Bazuln/DC/USEPA/US@EPA, Ray Kent/DC/USEPA/US@EPA, Mah Shamim/DC/USEPA/US@EPA, Jose Melandez/DC/USEPA/US@EPA, James Folkel/DC/USEPA/US@EPA, Abdellah Khasawinah/DC/USEPA/US@EPA, Timothy Leighton/DC/USEPA/US@EPA, David Hrdy/DC/USEPA/US@EPA, Gary Otakle/DC/USEPA/US@EPA, Stove Jarboe/DC/USEPA/US@EPA, Nicole Zim/DC/USEPA/US@EPA, Mojmir Mazur/DC/USEPA/US@EPA, Alan Halvorson/DC/USEPA/US@EPA

cc: Michael Goodla/DC/USEPA/US@EPA, Neil Andercon/DC/USEPA/US Subject: Heads Up - NAA - Old Chemicals Briefing for Jim Jones on March 25

Jim Jones has asked to be briefed on NAA in Old Chemicals. The briefing has been scheduled for Thursday, March 25th. SRRD is hosting a pre-meeting meeting on Tuesday, March 23rd at 11:00 AM.

I also will schedule a team meeting the week before to give the team an opportunity to review the draft briefing paper and provide comments. Jim Jones is asking that the science division reps plan a speaking themselves when discussing their part of the risk assessments.

Mark

Mark T Howard
Chemical Review Manager
Special Review & Reregistration Division
Office of Pesticide Programs - US EPA
(703) 308-8172
(703) 308-8005 (f)
howard.markt@eps.gov



To: Susan Hummel/DC/USEPA/US

cc:

cc: John Bezuin/DC/USEPA/US@EPA

Subject: Re: NAA, Potassium salt

Sue,

I cannot find the April 2001 e-mail concerning the acceptability of doubling the use rate for NAA on d'Anjou pears that Amelia Aclerto says she sent to Cynthia Giles-Parker. It is not in the SLN jackets and not in the NAA files in my office. I also have no recollection of ever having seen this e-mail (the note to the file I placed in each of the SLN jackets is an effort to explain the significance of the documentation that follows, in lieu of a more expansive e-mail or memo).

John Bazuin

<<<<0>>>>

Susan Hummel



Susan Hummol

12/01/03 02:32 PM

To: John Bazuin/DC/USEPA/US@EPA

ce:

Subject: NAA, Potassium salt

Maybe you can answer this. Amelia is out of the office this week. The 24 #'s are WA010003, WA010004, OR010002, and OR010003.

Sue

---- Forwarded by Susan Hummel/DC/USEPA/US on 12/01/2003 02:32 PM ----



Susan Hummel

To: Amelia Acierto/DC/USEPA/US@EPA

cc:

12/01/2003 11:18 AM

Subject: NAA, Potassium salt

According to OPPIN, you worked on a 24C for NAA Potassium salt (056003), and wrote a review dated 7 Jun 2001. I can't find any copy of this review anywhere. I've looked in the Chemb database, on drive T: under tox and chemistry and risk. Can you tell me where it is?

Thanks.

Sue Hummel, Chemist Branch Senior Scientist Health Effects Division EPA Office of Pesticide Programs 1200 Pennsylvania Ave., NW (7509C) Washington, DC 20460-0001 703-305-7689



To: Susan Hummel/DC/USEPA/US

ce:

cc: John Bazuln/DC/USEPA/US@EPA

Subject: Re: NAA, Potassium selt

I should be able to find this. Hope to get back to you tomorrow morning.

John Bazuin

<<<<0>>>>

Susan Hummel



Susan Hummal 12/01/03 02:32 PM

To: John Bazuin/DC/USEPA/US@EPA

cc:

Subject: NAA, Potassium salt

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Sue

--- Forwarded by Susen Hummel/DC/USEPA/US on 12/01/2003 02:32 PM ----



Susan Hummel

12/01/2003 11:18 AM

To: Amelia Acierto/DC/USEPA/US@EPA

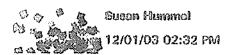
cc:

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To: John Bazuin/DC/USEPA/US@EPA

cc:

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Sug

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Susan Hummel

To: Amelia Ackerto/DC/USEPA/US@EPA

12/01/2003 11:18 AM _ _ ...

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Thanks.

Sue Hummel, Chemist Branch Senior Scientist Health Effects Division EPA Office of Pesticide Programs 1200 Pennsylvania Ava., NW (7509C) Washington, DC 20460-0001 703-305-7689



To: Susan Hummel/DC/USEPA/US

ce: Gary Otokio/DC/USEPA/US@EPA, Torosa

Downs/DC/USEPA/US@EPA

cc: John Bazuin/DC/USEPA/US@EPA, Gory Otakie/DC/USEPA/US@EPA, Teresa Downs/DC/USEPA/US@EPA

Subject: Ro: NAA MRID

All,

Just a guick (7) raply...to somewhat clarify. 64864-LN was "me-tooed" on 5481-430, an Amvac product. However, Amvac was not the original registrent of this product, Union Carbide was. UC, in their application cover letter, reference Accession No. 246499 for some of the Product Chemistry data. That was the link I made to get to the MRID Nos. I mentioned below. I have already returned the pertinent jackets to the Document Center, but could get them again, if needed, of course. I looked in the MRIDs I had blown back and found Color and Physical State in them in a cursory look. I did not immediately spot Odor, Storage Stability, pH, or Density, but the last two might be able to be taken from a CSF (8 of which were in the accession, apparently). On the other hand, if the question is what MRID did Bruce actually review, rather than what MRID(s) contain the relevant supporting Product Chemistry data, it is likely that only Bruce could say for sure...and he drew a blank on it at the time I asked him. In my opinion, the possibility of a TRID No. being involved is extremely small to start with, then to have to change one of the TRID's numbers and drop another of the TRID's numbers to get to the MRID No. of the document deemed to be the correct one has a vanishingly small possibility. By the way, yesterday Bruce asked me to let the problem mull in his mind for a short while...he thought there was at least a small chance that the correct answer would come to him. About Amvac, they besically bought the power position in NAA and its salts from Union Carbide, Greenwood Chemical Co. (a tiny, extinct Virginia company whose Virginia production site is now something like a Superfund site), and other companies. Arnvac has also fought vigorously for many years to maintain its power position in NAA and its salts. Amvae did not initiate this chemical...you often have to look back farther to discover the data that underpin the chemical.

John Bazuin

<<<<0>>>>

Susan Hummel



Susan Hummel 11/26/03 12:29 PM

To: John Bazuin/DC/USEPA/US@EPA

cc: Gary Otakie/DC/USEPA/US@EPA, Teresa

Downs/DC/USEPA/US@EPA

Subject: Re: NAA MRID

John,

I was looking for some way for that number (470....) to have appeared looking like an MRID on a study that Bruce could have reviewed. The first thing I checked was to see if the digits were mixed up, and there was no plausible match. Then I saw a paper copy of an older study that had an accession number. On the first page of the study (under the red cover sheet) was TRID 460.... (for the one that I looked at). At that point I became convinced that the number (470...) was a TRID. Teresa pointed out that a TRID had 9 digits rather than 8, and I thought someone just omitted a digit to make it look like an MRID.

Then I looked for Product chemistry studies for the 63 series, wrote down the MRID numbers for

titles that were possible metches, and asked Toresa to check the ones from Amvac first and then the rest if Amvac's didn't match. The TRID number matched (if you add a 0 at the end) one of the AMVAC studies. (The reason I suggested Amvac is that they are the technical registrant, so I would expect that anyone producing a product registration would have to be buying from them.

The only way to further confirm it would be to check the content of the study against Bruca Kitchen's review and confirm that they match.

Out of the accession number you listed these are the possible MRIDs: (MRID # wrapped)

- 87 Helfant, L.J.; Oestreicher, S.L. (1981) NAA Raw Material Evaluation: Registration Chemistry: File No.
- 89 29693. (Unpublished study received Dec 22, 1981 under 264-29; submitted by Union Carbide Agricultural
- 9 Products Co., Inc., Ambler, Pa.; CDL: 246499-A)
- 87 Greenwood Chemical Company (1977) Spec Sheet: Alpha Naphthalene Acetamide. Greenwood, Va.:
- 91 Greenwood Chemical. (Also-In-un-published submission received Aug 7, 1981 under 264-29; sub-mitted
- 3 by Union Carbide Agricultural Products Co., Inc., Ambler, Pa; CDL:246499-P)
- 87 Greenwood Chemical Company (1977) Specification Sheet: 1-Naphtha-lene Acetic Acid. Greenwood, Va.:
- 91 Greenwood Chemical. (Also 7-In-unpublished submission received Aug 7, 1981 under 264-29; submitted
- 4 by Union Carbide Agricultural Products Co., Inc., Ambler, Pa.; CDL:246499-Q)
- 87 Greenwood Chemical Company (19??) Alpha Naphthalene Acetic Acid (Sodium Sah): Specifications.
- 91 Greenwood, Va.: Greenwood Chem- ical. (Also-In-unpublished submission received Aug 7, 1981 under
- 5 264-29; submitted by Union Carbide Agricultural Products Co., Inc., Ambler, Pa.; CDL:246499-R)

I guess I don't understand how Union Carbide is involved, the product Bruce reviewed was File Smbol 64804-LN, which was registered to Pace LLC, and has been transfered to Amvac (It's NAA technical), EPA Reg. No. 5481-498. The only way would be if they are the source in the CSF. And then it would end up being an alternate source of technical for AMVAC. We can't continue the discussion on what may or may not be in the CSF in email.

In our chem chapter it states that Bruce's review was comparing the two technicals (It was apparently a me-too registration). So, he would look at data from AMVAC, but we should only be using Phys/chem properties where the test substance is the PAI. (not those based on the technical product)

Sue

John Bazuin



John Bazuin 11/26/2003 11:20 AM To: Susen Humms//DC/USEPA/US@EPA cc: Gary Otalde/DC/USEPA/US@EPA, Tereso

Downs/DC/USEPA/US@EPA

Subject: Ro: NAA MRID

All,

I'm not at all convinced that 160552 is the correct MRID No. Union Carbide specifically

references (in their registration package cover letter but not in their Data Matrix) Accession No. 246499 as being the source of the Product Chemistry data they cite (only a few GRNs; they also submitted some) during the registration process for the product that now has the Reg. No. 5481-430. Yesterday, John Jamula printed out for me the MRID Nos, that were derived from Accession No. 246499. There are 18 of them: 1) the continuous series 87899 thru 87915, and 2) 159291. (By the way, I also found out from JJ, and confirmed today, that the Accession-to-MRID translation can be done in OPPIN.) I looked up all of these MRID Nos. In OPPIN and found out that 8 of them are apparently CSFs (I). I have requested blow-backs of the other 10. In general, the physical volume contained an amalgam of Product Chemistry study-type documents that had to do with NAA plus its salts, esters, etc.

[Break in the response]

While I was responding I found out that the blowbacks were ready, so I'm now looking them over. Phys./chem. properties for NAA can be found in MRIDs No. 87899 (an attachment list) and 87914 (a spec. sheet that includes melting point and color). This is the most I can do with the information available to me. Does HED want to see the blow-backs? I have no need to retain them.

Yesterday I spent some time with Bruce Kitchens trying to figure out which MRID No. he'd been referring to but Bruce could not recall it. The MRID No. in that review is clearly not possible, nor could either of us permute that MRID No. into one that did work.

John Bazuin

Susan Hummel



Susan Hummel 11/26/03 10:33 AM To: Gary Otakio/DC/USEPA/US@EPA

cc: Teresa Downs/DC/USEPA/US@EPA, John Bazuin/DC/USEPA/US@EPA

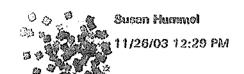
Subject: NAA MRID

The correct MRID for the NAA Prod Chem study is 00160552 (reviewed by Bruce Kitchens, 63 series Prod Chem data).

The number Bruce used turned out to be a TRID (with one digit missing), which is the number that is on the cover page of an older study that has an accession number.

BIG THANKS to Teresa Downs for checking the list of possible MRIDs for the right (or almost matching) TRID.

Sue Hummel, Chemist Branch Senior Scientist Health Effects Division EPA Office of Pesticide Programs 1200 Pennsylvania Ave., NW (7509C) Washington, DC 20460-0001 703-305-7689



To: John Bezuin/DC/USEPA/US@EPA

cc: Gary Otakie/DC/USEPA/US@EPA, Torosa

Downs/DC/USEPA/US@EPA

Subject: Re: NAA MRID

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- 91 Greenwood, Va.: Greenwood Chem-ical. (Also-In-unpublished submission received Aug 7, 1981 under
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Sue

John Bazuin



John Bazuin 11/26/2003 11:20 AM To: Susan Hummel/DC/USEPA/US@EPA cc: Gary Otekie/DC/USEPA/US@EPA, Toresa Downs/DC/USEPA/US@EPA

Subject: Re: NAA MHIDE

ΑII,

I'm not at all convinced that 160552 is the correct MRID No. Union Carbide specifically references (In their registration package cover letter but not in their Data Matrix) Accession No. 246499 as being the source of the Product Chemistry data they cite (only a few GRNs; they also submitted some) during the registration process for the product that now has the Reg. No. 5481-430. Yesterday, John Jamula printed out for me the MRID Nos. that were derived from Accession No. 246499. There are 18 of them: 1) the continuous series 87899 thru 87915, and 2) 159291. (By the way, I also found out from JJ, and confirmed today, that the Accession-to-MRID translation can be done in OPPIN.) I looked up all of these MRID Nos. In OPPIN and found out that 8 of them are apparently CSFs (I). I have requested blow-backs of the other 10. In general, the physical volume contained an amalgam of Product Chemistry study-type documents that had to do with NAA plus its salts, esters, etc.

[Break in the response]

While I was responding I found out that the blowbacks were ready, so I'm now looking them over. Phys./chem. properties for NAA can be found in MRIDs No. 87899 (an attachment list) and 87914 (a spec. sheet that includes melting point and color). This is the most I can do with the information available to me. Does HED want to see the blow-backs? I have no need to retain them.

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John Bazuin

Susan Hummel



Susan Hummal 11/26/03 10:33 AM

To: Gary Otakie/DC/USEPA/US@EPA

cc: Teresa Downs/DC/USEPA/US@EPA, John Bazuin/DC/USEPA/US@EPA

C. Lines NA A BABID

Subject: NAA MRID

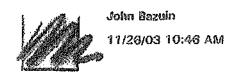
The correct MRID for the NAA Prod Chem study is 00160552 (reviewed by Bruce Kitchens, 63 series Prod Chem data).

The number Bruce used turned out to be a TRID (with one digit missing), which is the number that

is on the cover page of an older study that has an accession number.

BIG THANKS to Teresa Downs for checking the list of possible MRIDs for the right for almost matching) TRID.

Sue Hummel, Chemist Branch Senior Scientist Health Effects Division EPA Office of Pesticide Programs 1200 Pennsylvania Avo., NW (7509C) Washington, DC 20460-0001 703-305-7689



To: Susan Hummei/DC/USEPA/US

cc: Gary Otakie/DC/USEPA/US@EPA, Toresa Downe/DC/USEPA/US@EPA

cc: Gary Otakia/DC/USEPA/US@EPA, Terosa
Downs/DC/USEPA/US@EPA, John Bazuin/DC/USEPA/US@EPA

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cc: Teresa Downs/DC/USEPA/US@EPA, John

Bazuin/DC/USEPA/US@EPA

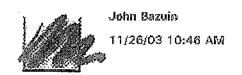
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To: Susan Hummel/DC/USEPA/US

cc: Gary Otakie/DC/USEPA/US@EPA, Teresa: Downs/DC/USEPA/US@EPA

cc: Gary Otakie/DC/USEPA/US@EPA, Teresa
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co: Teresa Downs/DC/USEPA/US@EPA, John

Bazuin/DC/UŞEPA/US@EPA

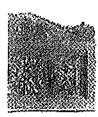
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Sue Hummel, Chemist Branch Senior Scientist Health Effects Division
EPA Office of Pesticide Programs
1200 Pennsylvania Ave., NW (7509C)
Washington, DC 20460-0001
703-305-7689



Tyler Lano 06/26/03 08:46 AM To: Abdallah Khasawinah/DC/USEPA/US@EPA, Alan Halvorson/DC/USEPA/US@EPA, Alan Vaughn/R6/USEPA/US@EPA, Cynthia Doucoure/DC/USEPA/US@EPA, David Hrdy/DC/USEPA/US@EPA, Dennis McNeilly/DC/USEPA/US@EPA, Gary Otakie/DC/USEPA/US@EPA, James Felkel/DC/USEPA/US@EPA, John Bazuin/DC/USEPA/US@EPA, Josa Melendaz/DC/USEPA/US@EPA, Mojmir Mazur/DC/USEPA/US@EPA, Nell Anderson/DC/USEPA/US@EPA, Nicole Mosz/DC/USEPA/US@EPA, Roger Clark/DC/USEPA/US@EPA, Steve Jarboz/DC/USEPA/US@EPA, Timothy Leighton/DC/USEPA/US@EPA

cc: Subject: New CRM

All-

Sorry, Mark will be the contact point for NAA.

Chemical Review Manager
Office of Pesticide Programs
Special Review and Reregistration Division

MC: 7508C

Phone #: (703) 305-2737 Fax #: (703) 308-8005



John Bazuin 06/26/03 08:58 AM To: Tyler Lane/DC/USEPA/US

cc:

cc: Abdallah Khasawinah/DC/USEPA/US@EPA, Alan Halvorson/DC/USEPA/US@EPA, Alan Vaughn/R6/USEPA/US@EPA,

Cynthia Doucoure/DC/USEPA/US@EPA, David

Hrdy/DC/USEPA/US@EPA, Dennis McMeilly/DC/USEPA/US@EPA,

Gary Otakie/DC/USEPA/US@EPA, James

Felkel/DC/USEPA/US@EPA, John Bazuin/DC/USEPA/US@EPA, Jose Melendez/DC/USEPA/US@EPA, Mojmir Mazur/DC/USEPA/US@EPA,

Nell Anderson/DC/USEPA/US@EPA, Nicole

Mosz/DC/USEPA/US@EPA, Roger Clark/DC/USEPA/US@EPA, Stove

Jarboe/DC/USEPA/US@EPA, Timothy

Leighton/DC/USEPA/US@EPA, MarkT Howard/DC/USEPA/US@EPA

Subject: Re: New CRM

Tyler,

I wish you good luck in grad, school. Hope you put aside some money so that you don't have to live like I did while I was in grad, school!

John Bazuin

Tyler Lane



Tyler Lene 06/26/03 08:42 AM To: Abdallah Khasawinah/DC/USEPA/US@EPA, Alan
Halvorson/DC/USEPA/US@EPA, Alan Vaughn/R8/USEPA/US@EPA,
Cynthia Doucoure/DC/USEPA/US@EPA, David
Hrdy/DC/USEPA/US@EPA, Dennis McMeilly/DC/USEPA/US@EPA,
Gary Otakie/DC/USEPA/US@EPA, James
Felkel/DC/USEPA/US@EPA, John Bezuin/DC/USEPA/US@EPA,
Jose Melandez/DC/USEPA/US@EPA, Mojmir
Mazur/DC/USEPA/US@EPA, Neil Anderson/DC/USEPA/US@EPA,
Nicole Mosz/DC/USEPA/US@EPA, Roger

Clark/DC/USEPA/US@EPA, Steve Jarbos/DC/USEPA/US@EPA, Timothy Leighton/DC/USEPA/US@EPA

cc: MarkT Howard/DC/USEPA/US@EPA

Subject: New CRM

All-

I will be returning to school for a Master's Degree in Hazardous Substances and taking a leave of absence from EPA. Mark Howard will now be the Chemical Review Manager contact point. Thank you all for the work you have put into the reregistration process so far and it was great working with you.

Tylor

Chemical Review Manager
Office of Posticide Programs
Special Review and Reregistration Division

MC: 7508C

Phone #: (703) 305-2737 Fax #: (703) 308-8005



Tylor Lano 06/26/03 08:42 AM

To: Abdellah Khasawinah/DC/USEPA/US@EPA, Alan Halverson/DC/USEPA/US@EPA, Alan Vaughn/RG/USEPA/US@EPA. Cynthia Doucoure/DC/USEPA/US@EPA, David Hrdy/DC/USEPA/US@EPA, Dennis McNeilly/DC/USEPA/US@EPA, Gary Otakie/DC/USEPA/US@EPA, Jamas Felkel/DC/USEPA/US@EPA, John Bazuin/DC/USEPA/US@EPA, Jose Melendez/DC/USEPA/US@EPA, Mojmir Mazur/DC/USEPA/US@EPA, Neil Anderson/DC/USEPA/US@EPA, NIcole Mosz/DC/USEPA/US@EPA, Roger Clark/DC/USEPA/US@EPA, Steve Jarboo/DC/USEPA/US@EPA, Timothy Leighton/DC/USEPA/US@EPA

cc: MarkT Howard/DC/USEPA/US@EPA

Subject: New CRM

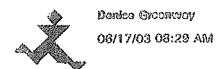
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Chemical Review Manager Office of Pesticide Programs Special Review and Reregistration Division MC: 7508C

Phone #: (703) 305-2737 Fax #: (703) 308-8005



To: John Bazuin/DC/USEPA/US@EPA

66:

Subject: thanks!

Thanksl

John,

I responded to your voice mail, but since I failed to press "#" afterwards, I'm unsure if it transmitted. Sooo, thanks for looking into my bird/seed question. I appreciate your effort and for the summary of the results. Sounds like there is some odd stuff out there!

I do have some ND oilseed contacts I may call to learn if birds feeding in the fields is a common thing, or even if birds might be a recognized pest for mustard seed producers. It is interesting that it is apparently not sold as bird seed. Maybe birds avoid it?

Before leaving, I heard from Abdallah that he was interested in the acute tox info I have for NAA, even though it pre-dates anything on his circulated list. I informed my Branch Chief of the location of the info, in case she wanted to furnish it to him before my return tomorrow. As there were no new voice or e-malls regarding this today, I do not know if the files were shared with Abdallah or not.

Thanks again, John!

Denise, 308-8263



To: Abdellah Khasowinch/DC/USEPA/US

cc: Ghazi Denman/DC/USEPA/US@EPA, Roy Kent/DC/USEPA/US@EPA

cc: John Bazuin/DC/USEPA/US@EPA, Ray Kont/DC/USEPA/US@EPA,

Ghazi Dannen/DC/USEPA/US@EPA

Subject: Ro: NAA & salts

Abdallah.

Have been out the past several days. About the draft Tox. DERs, it is certain that electronic versions are not present within RD. I'd think that your best bet here would be to talk to anybody in HED whose name is on the DERs or, if they are no longer available, to try anyone who has succeded them and/or the HED Document Center. I strongly doubt that electronic versions of these draft DERs ever left HED. As to the Acute Tox. DERs, I'm pretty sure I don't have them (but will look through my binders and see). Perhaps they are present in the jackets (what are the Reg. Nos. of the products?); you might also ask Denise Greenway in BPPD about them, last week she mentioned to me that she still had some Acute Tox. DERs for NAA and Salts.

John Bazuin

Abdallah Khasawinsh



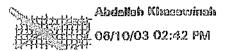
Abdaileh Khesawinah 06/10/03 02:42 PM Te: John Bezuin/DC/USEPA/US@EPA

cc: Rey Kent/DC/USEPA/US@EPA, Ghazi Dannan/DC/USEPA/US@EPA

Subject: NAA & salts

John. The package I got from you on NAA and salts was extremely helpful for me. It included DRAFT DERs of all the studies on my list except for the Acute Tox studies. Is it possible to trace those acute tox studies for their wherebouts? Another thing on the DRAFT DERs, Could you check if you (or some one else) may have the electronic discs of such drafts. These are needed badly to finalize the drafts. Your help is always appreciated.

Abdellah



To: John Bozuin/DC/USEPA/US@EPA

co: Ray Kont/DC/USEPA/US@EPA, Ghazi Dannan/DC/USEPA/US@EPA

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Abdatlah



Denise Greenway 08/05/03 07:53 AM To: John Bazuin/DC/USEPA/US@EPA

cc:

Subject: Re: Naphthalene Acetic Acld (NAA) and its salts

John,

Thanks for looking into this. Your research was fruitful. As expected, I have only old end use product-related amendment requests and copies of a few older (1980s) acute tox DERs (that were not on HED's list).

Denise



To: Sheryl Rellly/DC/USEPA/US, Abdallah Khasawinah/DC/USEPA/US, Roger Gardner/DC/USEPA/US, Tim McMahon/DC/USEPA/US, Ray Kent/DC/USEPA/US, Paula Deschamp/DC/USEPA/US, Stephen Dapson/DC/USEPA/US, Susan Makris/DC/USEPA/US, Tyler Lane/DC/USEPA/US

cc: Denise Greenwey/DC/USEPA/US, Richard Keigwin/DC/USEPA/US, Dennis McNeilly/DC/USEPA/US, Cynthia Gilos-Parker/DC/USEPA/US

CC:

Subject: Re: Naphthalene Acetic Acid (NAA) and its salte

All,

Denise was kind enough to bring this to my attention. I wanted to note that BPPD is not a player in this situation. NAA and Salts has always been an RD chemical except for ca. one year, during which BPPD took on this case because they felt it likely to effectively be a biorational type. During this time they did some preliminary work on their type of reregistration but did little else with the case. When NAA and Salts came back to RD. I hounded Denise about getting all the materials they had developed on the case, and RD finished all Actions that had appeared during the BPPD year. Thus, the fabled DERs, if they exist, could conceivably be In RD, but not in BPPD.

That brings up the puzzle. I've been working with NAA and Salts for a number of years now, and am not aware of any "large number of" recent tox. studies for this case. The only tox. studies that have been generated during my tenure with NAA, anyway, are a few 6-pack-type product-specific studies. I have also been through many (but by no means all) product jackets for NAA and Salts products without seeing much (if any) generic tox, data. However, somewhere along the way I did inherit (I did not record from who, and may not have known) the apparently final (have original signatures and dates) DERs for the following tox, studies: Chronic Oral/Carcinogenicity Feeding (using Na NAA), Chronic Oral (Capsule) Toxicity Study in the Beagle Dog (using Na NAA), 90-Day Oral (Feeding) Toxicity Study in the Ret (using Ethyl NAA), 13-Week Oral (Capsule) Toxicity Study in the Beagle Dog (as contrasted with a Beagle Snake, I suppose; used Ethyl NAA), Two-year Chronic Toxicity/Oncogenicity Study in Rats (interim report) (using Na NAA), 21-Day Repeated Dose Dermal Toxicity Study in the Rat (using Ethyl NAA), 21-Day Repeated Dose Dermal Toxicity Study in the Rat (using Naphthaleneacetamide), and 6 mutagenicity studies of several flavors of NAA. Most of these studies are dated 1996, but at least one is dated 1998. In addition, I have semioriginal DER-types dated 1994 for 21-Day Dermal Toxicity Study in Rets (using Na NAA), Subchronic Toxicity Study in Dogs (using Na NAA), Subchronic Toxicity Study in Rats (using Na NAA), and Subchronic Oral (Diet) Study (using Na NAA). The preceeding 4 DER-types specifically state that the studies were done for reregistration. I've also got a copy of a 1986 review of a Rabbit Teratology and Range Finding Study stating that it was done for the "NAA Registration Standard". Could some or all of these be what Abdullah is looking for? They have clearly never been filed in a jacket, and it looks as if they all (some obviously do) relate to reregistration. Wherever they came from, I snagged them and put them in a binder when I encountered them.

John Bazuin

<<<<0>>>>>

Forwarded by John Sazuin/DC/USEPA/US on 06/04/03 03:04 PM ----



Denise Greenway 06/04/03 09:54 AM To: John Bezuin/DC/USEPA/US@EPA

CC:

Subject: Re: Naphthalene Acetic Acid (NAA) and its salts

FVI, per conversation.

---- Forwarded by Danisa Greenway/DC/USEPA/US on 06/04/03 09:58 AM ----



Shoryl Rollly

To: Denise Greenway/DC/USEPA/US@EPA

06/04/03 09:15 AM

Subject: Re: Nephthelene Acotic Acid (NAA) and its salts

Denise, do you know if we still have any NAA DERs?

--- Forwarded by Shoryl Reilly/DC/USEPA/US on 06/04/2003 09:19 AM ----



Abdallah Khesawinah 06/04/2003 08:45 AM

To: Roger Gardner/DC/USEPA/US@EPA, Sharvi

Relliv/DC/USEPA/US@EPA, Tim McMahon/DC/USEPA/US@EPA

cc: Ray Kent/DC/USEPA/US@EPA, Paula Deschamp/DC/USEPA/US@EPA, Stephen Dapson/DC/USEPA/US@EPA

Subject: Re: Nephthelene Acetic Acid (NAA) and its calts

I have been referred to you for help on NAA tox studies reviews. There is a large number of recent tox studies on NAA or its salts without any available DERs. Please read below for the list of these studies. Stave Dapson of HED tells me that some of these studies were contracted out for review, but all the files were sent to BPPD since the material was not an insecticide but a growth regulator. Now NAA is returned back to HED for review. So I need your help in locating DERs, draft or final form.

Abdallah Khasawinah Toxicologist/RRB4/HED 703 305-1226

---- Forwarded by Abdellah Khasawinah/DC/USEPA/US on 06/04/2003 08:34 AM -----



Paula Deschamp

To: Abdellah Khasawinah/DC/USEPA/US@EPA

06/02/2003 04:37 PM

Subject: Re: Naphthalene Acetic Acid (NAA) and its acite(a)



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Abdallah Khasawinah



Abdellah Khasawinah 06/02/2003 08:50 AM

To: OPP HED RASS, OPP HED TOX

cc: Ray Kent/DC/USEPA/US@EPA, Paula Deschamp/DC/USEPA/US@EPA, Susan

Makria/DC/USEPA/US@EPA, Tyler Lano/DC/USEPA/US@EPA

Subject: Naphthalene Acetic Acid (NAA) and its salts

Hi Folks: I am reviewing the toxicology of NAA and its salts for presentation in the very near future to HIARC. I ran into the attached list of studies and I was unable to find any reviews (DERs) for any of them. According to SRRD files, these studies have been beaned to RAB3/TOX branch for review. I need your immediate help about their status. Thanks for any help you offer in this regard.

Abdallah Khasawinah

--- Forwarded by Abdellah Khasowinah/DC/USEPA/US on 05/02/2003 08:00 AM ---



Tylor Lano

To: Abdellah Khasawinah/DC/USEPA/US@EPA

oc:

05/30/2003 03:26 PM

Subject: Re: NAA

abdallah-

i have inserted the DP barcodes before the corresponding MRID. I hope this helps you track these DERs down-tyler



Tox Status.wp

Chemical Review Menager Office of Pesticide Programs Special Review and Reregistration Division

MC: 7508C

Phone #: (703) 305-2737 Fax #: (703) 308-8005 Abdallah Khasawinah



Denise Greenway

To: John Bazuin/DC/USEPA/US@EPA

06/04/03 09:54 AM

Subject: Re: Naphthalene Acetic Acid (NAA) and its salts

FVI, per conversation.

---- Forwarded by Danisa Greenway/DC/USEPA/US on 06/04/03 09:58 AM -----



Sheryl Rollly

To: Denise Greenway/DC/USEPA/US@EPA

CC:

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---- Forwarded by Sheryl Reilly/DC/USEPA/US on 06/04/2003 09:19 AM ----



Abdallah Khasawinah 06/04/2003 08:45 AM

06/04/03 09:15 AM

To: Roger Gardner/DC/USEPA/US@EPA, Sheryl

Reilly/DC/USEPA/US@EPA, Tim McMahon/DC/USEPA/US@EPA

cc: Ray Kent/DC/USEPA/US@EPA, Paula

Deschamp/DC/USEPA/US@EPA, Stephen

Dapson/DC/USEPA/US@EPA

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Paula Deschamp

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06/02/2003 08:50 AM

To: OPP HED RAB3, OPP HED TOX

cc: Ray Kent/DC/USEPA/US@EPA, Paula Deschamp/DC/USEPA/US@EPA, Susan

Makris/DC/USEPA/US@EPA, Tylor Lane/DC/USEPA/US@EPA

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---- Forwarded by Abdallah Khasawinah/DC/USEPA/US on 06/02/2003 08:00 AM ----



Tyler Lane

To: Abdallah Khasawinah/DC/USEPA/US@EPA

05/30/2003 03:26 PM

Subject: Re: NAA

abdallah-

i have inserted the DP barcodes before the corresponding MRID. I hope this helps you track these DERs down-tyler



Tox Status.wp

Chemical Review Manager
Office of Pesticide Programs
Special Review and Reregistration Division

MC: 7508C

Phone #: (703) 305-2737 Fax #: (703) 308-8005 Abdallah Khasawinah



To: John Bazuin/DC/USEPA/US@EPA

cc:

Subject: Jacket 284-29 from the FRC

John -

We have been notified by the FRC that the jacket, 264-29, that you recently requested be retrieved for you cannot be located and we are unable to get it for you.

Sorry for the inconvenience - Donna



Onel rehit 04/17/03 09:48 AM To: John Bazuin/DC/USEPA/US@EPA

cc:

Subject: Ro: NAA Acute Tox. study®

thanks much.

Chemical Review Manager Office of Pesticide Programs Special Review and Reregistration Division

MC: 7508C

Phone #: (703) 305-2737 Fax #: (703) 308-8005

John Bazuin



John Bazuln

To: Tyler Lane/DC/USEPA/US@EPA

ce:

Subject: NAA Acute Tox. atudy

Tylor,

The Acute Tox. study mentioned by Amvac at the SMART meeting is an Acute Eye Irritation study for Reg. No. 5481-429 (Tre-Hold Sprout Inhibitor A-112). The a.i. here is Ethyl 1naphthalaneacetic acid. We got the Action (which also includes a revised Basic CSF and an amended label) on 3/17/03, the Beans went into review on 3/31/03, the Beans are due back on 5/15/03, and we are scheduled to report back to Amvac by 6/15/03. With this Action Amvac is seeking to reduce the Signal Word Intensity from DANGER to WARNING and remove the "flammability" statement from the label.

John Bazuin

Arthur Grube

04/17/03 09:45 AM

To: John Bazum/DC/USEPA/US@EPA

cc: Abdallah Khasawinah/DC/USEPA/US@EPA, Alan

Halvorson/DC/USEPA/US@EPA, Allan Vaughan/DC/USEPA/US@EPA, Cynthia

Doucoure/DC/USEPA/US@EPA, Dava Jaquith/DC/USEPA/US@EPA,

David Widawsky/DC/USEPA/US@EPA, Dennis

McNeilly/DC/USEPA/US@EPA, Gary Otakie/DC/USEPA/US@EPA,

Jose Molendez/DC/USEPA/US@EPA, Mah

Shamim/DC/USEPA/US@EPA, Michael Goodis/DC/USEPA/US@EPA,

Mojmir Mazur/DC/USEPA/US@EPA, Neil

Anderson/DC/USEPA/US@EPA, Nicole Mosz/DC/USEPA/US@EPA, Rafael Prieto/DC/USEPA/US@EPA, Ray Kent/DC/USEPA/US@EPA,

Richard Dumas/DC/USEPA/US@EPA, Richard

Keigwin/DC/USEPA/US@EPA, Roger Clark/DC/USEPA/US@EPA,

Steve Jarboe/DC/USEPA/US@EPA, Timothy

Loighton/DC/USEPA/US@EPA, Tyler Lane/DC/USEPA/US@EPA

Subject: Ro: NAA Reregistration

John

You are not the only one who had a problem with the tables. I am going to revise the format for future use.

Art John Bazuin



John Bazuin 04/16/2003 03:16 PM To: Arthur Grubo/DC/USEPA/US@EPA

cc: Abdallah Khasawinah/DC/USEPA/US@EPA, Alan

Halvoreon/DC/USEPA/US@EPA, Allen Veughen/DC/USEPA/US@EPA, Cynthia

Doucoure/DC/USEPA/US@EPA, Dave Jequith/DC/USEPA/US@EPA,

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Jose Melandez/DC/USEPA/US@EPA, Mah

Shemim/DC/USEPA/US@EPA, Michael Goodia/DC/USEPA/US@EPA,

Mojmir Mezur/DC/USEPA/US@EPA, Neil

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Stove Jarboo/DC/USEPA/US@EPA, Timothy

Leighton/DC/USEPA/US@EPA, Tyler Lane/DC/USEPA/US@EPA

Subject: Re: NAA Reregistration

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John B.



Arthur Grube

Arthur Grube

04/18/03 01:34 PM

To: Tylar Lans/DC/USEPA/US@EPA

cc: Abdallah Khasawinah/DC/USEPA/US@EPA, Alan

Halvorson/DC/USEPA/US@EPA, Allen Vaughan/DC/USEPA/US@EPA, Cynthie

Doucoure/DC/USEPA/US@EPA, Dave Jaquith/DC/USEPA/US@EPA,

Dennis McNeilly/DC/USEPA/US@EPA, Gary

Otakie/DC/USEPA/US@EPA, John Bazuin/DC/USEPA/US@EPA, Jose Molendez/DC/USEPA/US@EPA, Mah Shamim/DC/USEPA/US@EPA,

Michael Goodis/DC/USEPA/US@EPA, Mojmir

Mazur/DC/USEPA/US@EPA, Neil Anderson/DC/USEPA/US@EPA,

Nicole Mosz/DC/USEPA/US@EPA, Rafsel

Prieto/DC/USEPA/US@EPA, Ray Kont/DC/USEPA/US@EPA, Richard Dumas/DC/USEPA/US@EPA, Richard Keigwin/DC/USEPA/US@EPA,

Roger Clark/DC/USEPA/US@EPA, Steve Jarboe/DC/USEPA/US@EPA, Timothy Leighton/DC/USEPA/US@EPA, David Widawsky/DC/USEPA/US@EPA

Subject: Re: NAA Rorogistration

Attached is screening level usage date for agricultural uses of NAA

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I would appreciate feedback on the usefulness of this file format. I can easily provide a DBF file if that would be more useful.

M

A002d5b.lst

Arthur H. Grube Ph.D.
Senlor Economist
EPA Office of Pesticide Programs
1200 Pennsylvania Avenue, NW (7503C)
Washington, DC 20460
(703) 308-8095 FAX (703) 308-8090
grubs.arthur@epa.gov

sbove is US Postal Service address only for FEDEX, UPS etc address is 9th Floor, Crystal Mall 2. 1921 Jefferson Davis Highway, Arlington VA 22202

Tyler Lane

Tyler Lana 04/02/2003 10:48 AM To: Abdallah Khasawinah/DC/USEPA/US@EPA, Alan Halvorson/DC/USEPA/US@EPA, Allen Vaughan/DC/USEPA/US@EPA, Arthur Gruba/DC/USEPA/US@EPA, Cynthia Doucoure/DC/USEPA/US@EPA, Dave Jaquith/DC/USEPA/US@EPA, Dennis McNeilly/DC/USEPA/US@EPA, Gary Otakio/DC/USEPA/US@EPA, John Bazuin/DC/USEPA/US@EPA, Mah Shamim/DC/USEPA/US@EPA, Michael Goodis/DC/USEPA/US@EPA, Mojmir Mozur/DC/USEPA/US@EPA, Noil Anderson/DC/USEPA/US@EPA, Nicole Mosz/DC/USEPA/US@EPA, Rafael Prioto/DC/USEPA/US@EPA, Ray Kent/DC/USEPA/US@EPA, Richard Dumas/DC/USEPA/US@EPA, Richard Kelgwin/DC/USEPA/US@EPA, Roger Clark/DC/USEPA/US@EPA, Steve Jarboo/DC/USEPA/US@EPA, Timothy Leighton/DC/USEPA/US@EPA, Jose Melendez/DC/USEPA/US@EPA

cc:

Subject: NAA Reregistration

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Attached you will find a contact list for the NAA reregistration team. If any adjustments need to be made to this list, please contact me. Also, I've sent a rough draft of a Guideline Status Table that I have been updating from a variety of sources to keep track of the status of any required studies. If any of you have updates to this list, please send them to me. I have sent a status report to the registrent which I will use to cross-check against our databases and update as necessary. If any of you have further questions, feel free to contact me and I look forward to seeing you on the 9th.

Tyler

Chemical Review Manager Office of Pesticide Programs Special Review and Reregistration Division

MC: 7508C

Phone #: (703) 305-2737 Fax #: (703) 308-8005





NAA Reregistration Team Guideline Status 3-25-03.



John Bazuin 04/17/03 09:26 AM

To: Tyler Lane/DC/USEPA/US

ce:

Subject: NAA Acute Tox. study

Tyler,

The Acute Tox. study mentioned by Amvac at the SMART meeting is an Acute Eye Irritation study for Reg. No. 5481-429 (Tre-Hold Sprout Inhibitor A-112). The a.i. here is Ethyi 1-naphtheleneacetic acid. We got the Action (which also includes a revised Basic CSF and an amended label) on 3/17/03, the Beans went into review on 3/31/03, the Beans are due back on 5/15/03, and we are scheduled to report back to Amvac by 6/15/03. With this Action Amvac is seeking to reduce the Signal Word intensity from DANGER to WARNING and remove the "flammability" statement from the label.

John Bazuin



Tylor Lane

04/16/03 03:18 PM

To: John Bazuin/DC/USEPA/US@EPA

cc:

Subject: Re: NAA Reregistration 🔯

thanks, John. I ended up doing the same type of reformatting in wordperfect.

Chemical Review Manager
Office of Pesticide Programs
Special Review and Reregistration Division

MC: 7508C

Phone #: (703) 305-2737 Fax #: (703) 308-8005

John Bazuin



John Bazuin

04/18/03 03:16 PM

To: Arthur Grube/DC/USEPA/US@EPA

cc: Abdellah Khasawinah/DC/USEPA/US@EPA, Alan

Holvorson/DC/USEPA/US@EPA, Allon Veughan/DC/USEPA/US@EPA, Cynthia

Doucoure/DC/USEPA/US@EPA, Dave Jaquith/DC/USEPA/US@EPA,

David Widowsky/DC/USEPA/US@EPA, Dennis

McNeilly/DC/USEPA/US@EPA, Gary Otakie/DC/USEPA/US@EPA,

Jose Melendez/DC/USEPA/US@EPA, Mah

Shamim/DC/USEPA/US@EPA, Michael Goodis/DC/USEPA/US@EPA,

Mojmir Mezur/DC/USEPA/US@EPA, Nell

Anderson/DC/USEPA/US@EPA, Nicole Mosz/DC/USEPA/US@EPA, Rafael Prieto/DC/USEPA/US@EPA, Ray Kent/DC/USEPA/US@EPA,

Richard Dumas/DC/USEPA/US@EPA, Richard

Keigwin/DC/USEPA/US@EPA, Roger Clerk/DC/USEPA/US@EPA,

Steve Jarboe/DC/USEPA/US@EPA, Timothy

Leighton/DC/USEPA/US@EPA, Tyler Lano/DC/USEPA/US@EPA

Subject: Ra: NAA Reregistration

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John B.



NAA.somesort.ofSAS.derived.file.20030

Arthur Grube

Arthur Grube

To: Tyler Lane/DC/USEPA/US@EPA

04/16/03 01:34 PM

cc: Abdallah Khasawinah/DC/USEPA/US@EPA, Alan

Halvorson/DC/USEPA/US@EPA, Allen Vaughan/DC/USEPA/IJS@EPA, Cynthia Doucoure/DC/USEPA/US@EPA, Dave Jaquith/DC/USEPA/US@EPA, Dennis McNeilly/DC/USEPA/US@EPA, Gory Otakie/DC/USEPA/US@EPA, John Bezuin/DC/USEPA/US@EPA, John Melendez/DC/USEPA/US@EPA, Meh Shamim/DC/USEPA/US@EPA, Michael Goodis/DC/USEPA/US@EPA, Mojmir Mazur/DC/USEPA/US@EPA, Neil Anderson/DC/USEPA/US@EPA, Nicole Mosz/DC/USEPA/US@EPA, Refsel Prieto/DC/USEPA/US@EPA, Refsel Prieto/DC/USEPA/US@EPA, Richard Dumas/DC/USEPA/US@EPA, Richard Keigwin/DC/USEPA/US@EPA, Roger Clark/DC/USEPA/US@EPA, Steve Jarboe/DC/USEPA/US@EPA, Timothy Leighton/DC/USEPA/US@EPA, David

Subject: Re: NAA Reregistration

Widawsky/DC/USEPA/US@EPA

Attached is screening level usage data for agricultural uses of NAA

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I would appreciate feedback on the usefulness of this file format. I can easily provide a DBF file if that would be more useful.

MI.

A002d5b.lst

Arthur H. Grube Ph.D.
Senior Economist
EPA Office of Pesticide Programs
1200 Pennsylvania Avenue, NW (7503C)
Washington, DC 20460
(703) 308-8095 FAX (703) 308-8090
grube.arthur@epa.gov

above is US Postal Service address only for FEDEX, UPS etc address is 9th Floor, Crystal Mall 2. 1921 Jefferson Davis Highway, Arlington VA 22202 Tyler Lane



Tyler Lane 04/02/2003 10:46 AM To: Abdellah Khasowinah/DC/USEPA/US@EPA, Alan Halvorson/DC/USEPA/US@EPA, Allan Vaughan/DC/USEPA/US@EPA, Arthur Grube/DC/USEPA/US@EPA, Cynthia Doucoure/DC/USEPA/US@EPA, Dave Jaquith/DC/USEPA/US@EPA, Dennis McNeilly/DC/USEPA/US@EPA, Gary Otekie/DC/USEPA/US@EPA, John Bazuin/DC/USEPA/US@EPA, Mah Shamim/DC/USEPA/US@EPA, Michael Goodis/DC/USEPA/US@EPA, Mojmir Mazur/DC/USEPA/US@EPA, Noil Anderson/DC/USEPA/US@EPA, Ray



Kont/DC/USEPA/US@EPA, Richard Dumas/DC/USEPA/US@EPA, Richard Keigwin/DC/USEPA/US@EPA, Roger Clark/DC/USEPA/US@EPA, Steve Jarbos/DC/USEPA/US@EPA, Timothy Leighton/DC/USEPA/US@EPA, Jose Melendez/DC/USEPA/US@EPA

cc:

Subject: NAA Reregistration[3]

All,

Attached you will find a contact list for the NAA reregistration team. If any adjustments need to be made to this list, please contact me. Also, I've sent a rough draft of a Guideline Status Table that I have been updating from a variety of sources to keep track of the status of any required studies. If any of you have updates to this list, please send them to me. I have sent a status report to the registrant which I will use to cross-check against our databases and update as necessary. If any of you have further questions, feel free to contact me and I look forward to seeing you on the 9th.

Tyler

Chemical Review Manager
Office of Pesticide Programs
Special Review and Reregistration Division
MC: 7508C

Phone #: (703) 305-2737

Fax #: (703) 308-8005

NAA Reregistration Team Guideline Status 3-25-03.



To: Arthur Grube/DC/USEPA/US

cc: Abdallah Khasawinah/DC/USEPA/US@EPA, Alan

Halvorson/DC/USEPA/US@EPA, Allen

Voughen/DC/USEPA/US@EPA, Cynthia

Doucoure/DC/USEPA/US@EPA, Dave Jaquith/DC/USEPA/US@EPA. David Widawsky/DC/USEPA/US@EPA, Dannis

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Richard Dumas/DC/USEPA/US@EPA, Richard

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Steve Jarboa/DC/USEPA/US@EPA, Timothy

Leighton/DC/USEPA/US@EPA, Tyler Lane/DC/LISEPA/US@EPA

cc: Tyler Lane/DC/USEPA/US@EPA, Abdelish Kheeawineh/DC/USEPA/US@EPA, Alan Helvorson/DC/USEPA/US@EPA. Allen Vaughan/DC/USEPA/US@EPA, Cynthia

Doucoure/DC/USEPA/US@EPA, Dave Jaquith/DC/USEPA/US@EPA,

Dennis McNeilly/DC/USEPA/US@EPA, Gary

Otekia/DC/USEPA/US@EPA, John Bazuin/DC/USEPA/US@EPA, Josa Melendez/DC/USEPA/US@EPA, Meh Shamim/DC/USEPA/US@EPA,

Michael Goodis/DC/USEPA/US@EPA, Molmir

Mazur/DC/USEPA/US@EPA, Neil Anderson/DC/USEPA/US@EPA,

Nicole Mosz/DC/USEPA/US@EPA, Refeel

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Subject: Re: NAA Reregistration

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Arthur Gruba

Anhur Grube

To: Tyler Lane/DC/USEPA/US@EPA

04/16/03 01:34 PM

cc: Abdallah Khasawinsh/DC/USEPA/US@EPA, Alan

Halverson/DC/USEPA/US@EPA, Allen Vaughan/DC/USEPA/US@EPA, Cynthia Doucoure/DC/USEPA/US@EPA, Dave Jaquitty/DC/USEPA/US@EPA, Dannis McNeilly/DC/USEPA/US@EPA, Gary
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Mazur/DC/USEPA/US@EPA, Neil Anderson/DC/USEPA/US@EPA, Nicole Mooz/DC/USEPA/US@EPA, Rafael
Prioto/DC/USEPA/US@EPA, Ray Kent/DC/USEPA/US@EPA, Richard
Dumas/DC/USEPA/US@EPA, Richard Kelgwin/DC/USEPA/US@EPA,
Roger Clark/DC/USEPA/US@EPA, Steve
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Lelghton/DC/USEPA/US@EPA, David
Widawsky/DC/USEPA/US@EPA

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Kent/DC/USEPA/US@EPA, Richard Dumos/DC/USEPA/US@EPA, Richard Kaigwin/DC/USEPA/US@EPA, Roger Clerk/DC/USEPA/US@EPA, Steve Jerboe/DC/USEPA/US@EPA. Timothy Leighton/DC/USEPA/US@EPA, Jose Melendez/DC/USEPA/US@EPA

CC:

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Tyler

Chemical Review Menager
Office of Pesticide Programs
Special Review and Reregistration Division
MC: 7508C

Phone #: (703) 305-2737

Fax #: 1703) 308-8005

NAA Reregistration Team Guideline Status 3-25-03.

Wednesday, April 16, 2003 11:59

Screening Level Estimates of Agricultural Uses of NAA Sorted Alphabetically

| 0.70.5 | | Pounds of Active | Percent of Crop |
|--------|----------------------|------------------|--------------------|
| OBS | Crop | Ingredient | Treated |
| 1 | Apples | 1,000 | 5 |
| 2 | Chemies | <500 | 5 |
| 3 | Grapes (CA only) | <500 | |
| 4 | Lemons (CA only) | <500 | |
| 5 | Olives | 1,000 | 5 |
| 6 | Oranges (CA only) | <500 | |
| 7 | Peaches | <500 | 5 |
| 8 | Pears | 3,000 | 50 |
| 9 | Tangerines (CA only) | < 500 | |
| 10 | Walnuts (CA only) | <500 | |

All numbers rounded.

Ç.S

^{&#}x27;<500' indicates less than 500 pounds of active ingredient.

^{&#}x27;<2.5' indicates less than 2.5 percent of crop is treated.

⁽CA only)' indicates information was available only for California. Use of NAA may have occurred in other states

Screening Level Estimates of Agricultural Uses of NAA Sorted by descending quantity of NAA applied to each crop

| | | Pounds of Active | Percent of Crop |
|-----|----------------------|---------------------|--------------------|
| OBS | Стор | Ingredient | Treated |
| 1 | Pears | 3,000 | 50 |
| 2 | Apples | 1,000 | 5 |
| 3 | Olives | 1,000 | 5 |
| 4 | Cherries | <500 | 5 |
| 5 | Peaches | <500 | 5 |
| 6 | Grapes (CA only) | <500 | |
| 7 | Lemons (CA only) | <500 | |
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| 9 | Tangerines (CA only) | <500 | |
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All numbers rounded.

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⁽CA only) indicates information was available only for California. Use of NAA may have occurred in other states.

Screening Level Estimates of Agricultum Uses of NAA Sorted by descending percent of crop treated with NAA

| OBS | Crop | Pounds of Active Ingredient | Percent of Crop Treated |
|-----|----------------------|-----------------------------------|-------------------------------|
| 3 | Pears | 3,000 | 50 |
| 2 | Apples | 1,000 | 5 |
| 3 | Olives | 1,000 | 5 |
| Ą | Cherries | <500 | 5 |
| 5 | Peaches | <500 | 5 |
| 6 | Grapes (CA only) | <500 | |
| 7 | Lemons (CA only) | <500 | |
| 8 | Oranges (CA only) | <500 | |
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Arthur Grubo

04/16/03 01:34 PM

To: Tyler Lene/DC/USEPA/US@EPA

sc: Abdelleh Khasowineh/DC/USEPA/US@EPA, Alan

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Michael Goodie/DC/USEPA/US@EPA, Moimir

Mazur/DC/USEPA/US@EPA, Noil Andorson/DC/USEPA/US@EPA.

Nicola Moaz/DC/USEPA/US@EPA, Rafaal

Prieto/DC/USEPA/US@EPA, Ray Kent/DC/USEPA/US@EPA, Richard Dumas/DC/USEPA/US@EPA, Richard Keigwin/DC/USEPA/US@EPA,

Roger Clerk/DC/USEPA/US@EPA, Steve Jerboe/DC/USEPA/US@EPA, Timothy Leighton/DC/USEPA/US@EPA, David Widawsky/DC/USEPA/US@EPA

Subject: Re: NAA Reregistration



The file is an ASCII text file with printer control characters at the top of the file. If you send it directly to the printer it should print out OK. You can also look at by first opening WordPerfect or equivalent and then opening the file. You will need to use a fixed font in a small point size to avoid line wrapping.

I would appreciate feedback on the usefulness of this file format. I can easily provide a DBF file if that would be more useful.

M

ACO2d5b.lst

Arthur H. Grube Ph.D.
Senior Economist
EPA Office of Pesticide Programs
1200 Pennsylvania Avenue, NW (7503C)
Washington, DC 20460
(703) 308-8095 FAX (703) 308-8090
grube.arthur@epa.gov

above is US Postal Service address only for FEDEX, UPS etc address is 9th Floor, Crystal Mall 2. 1921 Jefferson Davie Highway, Arlington VA 22202 Tyler Lane



Tyler Lane 04/02/2003 10:48 AM

To: Abdellah Khasawinah/DC/USEPA/US@EPA, Alan Halvorson/DC/USEPA/US@EPA, Allan Vaughan/DC/USEPA/US@EPA, Arthur Gruba/DC/USEPA/US@EPA, Cynthia Doucoura/DC/USEPA/US@EPA, Dava Jaquith/DC/USEPA/US@EPA, Dennis McNeilly/DC/USEPA/US@EPA, Gary Otakio/DC/USEPA/US@EPA, John Bazuin/DC/USEPA/US@EPA,



Meh Shamim/DC/USEPA/US@EPA, Michael Goodis/DC/USEPA/US@EPA, Mojmir Mazur/DC/USEPA/US@EPA, Neil Anderson/DC/USEPA/US@EPA, Nicole Mosz/DC/USEPA/US@EPA, Rafael Pristo/DC/USEPA/US@EPA, Ray Kent/DC/USEPA/US@EPA, Richard Dumas/DC/USEPA/US@EPA, Richard Keigwin/DC/USEPA/US@EPA, Roger Clerk/DC/USEPA/US@EPA, Steve Jarboe/DC/USEPA/US@EPA, Timothy Leighton/DC/USEPA/US@EPA, Jose Molendez/DC/USEPA/US@EPA

cc:

Subject: NAA Reregistration

All,

Attached you will find a contact list for the NAA reregistration team. If any adjustments need to be made to this list, please contact me. Also, I've sent a rough draft of a Guideline Status Table that I have been updating from a variety of sources to keep track of the status of any required studies. If any of you have updates to this list, please send them to me. I have sent a status report to the registrant which I will use to cross-check against our databases and update as necessary. If any of you have further questions, feel free to contact me and I look forward to seeing you on the 9th.

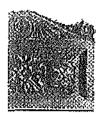
Tyler

Chemical Review Manager
Office of Pesticide Programs
Special Review and Reregistration Division
MC: 7508C

Phone #: (703) 305-2737

Fax #: (703) 308-8005

NAA Reregistration Team Guideline Status 3-25-03.



Tyler Lane 04/21/03 06:56 PM

To: Abdallah Khasawinah/DC/USEPA/US@EPA, Alan
Halvorson/DC/USEPA/US@EPA, Alan
Vaughn/R6/USEPA/US@EPA, Cynthia
Doucoure/DC/USEPA/US@EPA, David
Hrdy/DC/USEPA/US@EPA, Dennis
McNeilly/DC/USEPA/US@EPA, Gary
Otakie/DC/USEPA/US@EPA, James Felkel/DC/USEPA/US@EPA,
John Bazuin/DC/USEPA/US@EPA, Jose
Melendez/DC/USEPA/US@EPA, Mojmir
Mazur/DC/USEPA/US@EPA, Neil
Anderson/DC/USEPA/US@EPA, Nicole
Mosz/DC/USEPA/US@EPA, Roger Clark/DC/USEPA/US@EPA,
Steve Jarboe/DC/USEPA/US@EPA, Timothy
Leighton/DC/USEPA/US@EPA

00

Subject: NAA: SMART Meeting Minutes and Additional Information

All-

Attached you will find the minutes from the April 9th SMART Meeting. I am still awaiting comments from the registrant and will notify you if anything changes. I have been working on the Use Closure Memo and hope to have it to you in the next few weeks. If you have any further questions on this chemical, please contact me.

Tyler

Chemical Review Manager
Office of Pesticide Programs
Special Povings and Perceptuation F

Special Review and Reregistration Division

MC: 7508C

Phone #: (703) 305-2737 Fax #: (703) 308-8005





NAA SMART Meeting Minute Amvac NAA Presentation 4-9- Amvac Use Info 4-9-0

<u>DOCUMENT B</u>

What is the market niche for NAA?

The alternative to chemical thinning is hand labor, which is widely recognized as one of the most expensive inputs for orchard management. Hand thinning labor typically costs growers several hundred dollars or more per ocre. NAA is a relatively inexpensive post-bloom chemical thinning tool. NAA is used between the petal fall and 15 mm stage of apple development, which allows growers several potential opportunities to manage around ever-changing spring weather patterns for optimal results. NAA is also used in the fall at higher rates to prevent fruit from falling off the tree prematurely. There are few alternatives for pre-harvest drop, and NAA is recognized as an inexpensive tool.

What are the key pests or other conditions that drive the use of NAA? Please discuss on both a regional and national basis.

Many varieties of tree fruit produce biennially. Without thinning, trees would produce a large amount of small fruit one year, and a relatively small amount of large fruit the next. Growers use chemical thinning to maintain consistent production. It is also understood throughout the industry that chemical thinning typically results in increased bloom set the following year. With frost or hail damage a constant concern, growers prefer to start the season with as much bloom as they can possibly get.

Please describe all methods of application (air, ground, hand, chemigation, soil injection, etc.).

Thinning: A very high proportion of applications are made by ground via air-blast sprayers. Applications are designed to wet leaves to the point of drip, and sprays are typically directed toward the top 2/3 of the tree. Lower branches tend to thin more easily and are avoided by shutting off the spray nozzles that angle lower. However, aerial applications are to be retained on our labels.

Stop drop: Typical applications are made via air-blast sprayers. Some product is applied by airplane or helicopter. By air, applicators use t-jet nozzles and tank mix Regulaid to increase coverage. Helicopters keep short booms and limit nozzles to 20-24 in order to stay inside the rotor. Only Red Delicious and Golden Supreme varieties benefit from stop-drop applications. The East Coast has a significantly

higher usage for stop drop control.

Sucker pruning: Typically applied by hand-held sprayers or with a paintbrush or roller.

What are the maximum and average application rates?

Growers tend to use the upper end of labeled rates. For stop-drop on pears, an SLN label allows for a 50 gram rate (2x the label) in WA and OR.

Do these use rates differ from the maximum rates allowed on the label?

All rates fall within label recommended guidelines.

For food uses, what rates are supported by the submitted residue chemistry data?

All uses except pineapple (Import tolerance only).

How many applications (maximum and average) are made per season?

Thinning: A maximum of three applications are made in the spring for fruit thinning, and most growers average two applications. The best time for thinning is when the fruit is small, so once the optimal timing is past, applications stop.

Stop drop: One to two applications are made in the fall to prevent pre-harvest drop. Application costs make multiple stop-drop applications less feasible economically.

Return Bloom: One to four applications can be made throughout the summer for enhancement of return bloom. We estimate that less than 2% of all acres are treated for return bloom.

How many applications are made per crop or per year?

See above. There is a seasonal maximum of 50g per acre pre season for apples and pears and 25 g per acre or other crops.

What is the timing (months) of applications and re-treatment intervals (minimum, maximum and typical)?

Thinning applications typically take place in early spring, starting with California,

the East Coast and PNW, and finally Michigan and surrounding areas. Most of the thinning applications are made in May, and re-treatment intervals consistent for all uses, at about one to two weeks apart. For stop-drop applications are made in fall, generally when the first fruit begins to drop from tree. Re-treatments are made in two-week intervals. There is little variation between minimum and maximum re-treatment intervals, regardless of the use. Tre-Hold applications are typically one-time events.

Are there regional differences to these application patterns?

Every variety of tree fruit thins differently, and orchard blocks vary by overall plant vigor and weather patterns. As a result, growers in warmer areas such as southern WA typically use lower rates and different formulations than growers in cold areas such as Michigan.

How many acres are generally treated by an applicator per day and per season?

A sprayer will typically treat 20-40 acres on any given day. Helicopters and airplanes can treat up to 500 acres per day, but distances between applications locations inhibit efficiency. Tre-hold application (spray or paint) can be made at the rate of 20 trees per day.

Describe the types of worker activities impacted by re-entry intervals (REI) for NAA, including any restrictions (such as number of acres that can be treated by an individual). What is the typical length of pre-harvest intervals (PHIs) for different crops?

Two (2) day PHI for apples and pears, 150 days for citrus (oranges, tangerines, mandarins tangelos and tangors), and 30 day PHI for cherries. Few if any worker activities are impacted by thinning and stop drop, because thinning sprays occur prior to the onset of hand-thinning, and pre-harvest stop-drop applications take place well before harvest. According to PR Notice 95-3 NAA qualifies for a 4 hour reentry. Currently the REI is 48 hours.

Is NAA used as a post-horvest treatment to the horvested commodity or parent plant?

No.

Are concentration factors associated with post-horvest processing (washing. trimming. blanching), transport, storage, or cooking?

No.

Please describe equipment used for mixing, loading, and application especially for uncommon uses.

The most common application method is through an airblast sprayer. Product is mixed as the tank fills. Amid-Thin, Amcotone and Fruitone are powders, the rest liquids.

Will Amusc be supporting any special local needs (SLN) registrations? Yes. SLN for pears in WA/OR. Fruit Fix Conc. 200-CA-950010/Cherries, Fruitone N-OR-910028/Pears, K-Salt Fruit Fix 800-OR-910031/Apples/Pears, OR-010003/D'Anjou Pears, WA-010003/D'Anjou Pears, OR-910030/Apples, OR-010002/D'Anjou Pears, WA-910050/Apples/Pears, WA-010004/D-Anjou Pears, Tre-Hold A-112 / 5481-429 - CA-930013/Pomegranates

Are there any feeding/grazing restrictions on NAA product labels?

None except for not allowing livestock to graze in Cherry orchards treated with NAA.

Are there any other existing restrictions, such as for groundwater? Please describe specific uses and areas/sites to which the restriction applies.

. No

Are you aware of any metabolites or degradates of NAA?

There are no toxicological significant metabolites or degradates of NAA (or related compounds.

AMMAC CHEMICAL CORPORATION

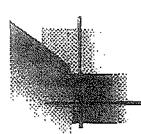
NAA and Derivative Products

EPA SMART Meeting 9 April 2003



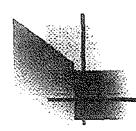
- > Introduction
- > Technical Registrations
- > End-Use Formulations
- > Available Data
- > Use Patterns



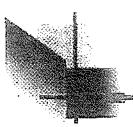


- > Introduction
 - > AMVAC will support:
 - > All its current registered labels
 - > All its current registered uses including:
 - > All the maximum label rates
 - > All the maximum number of applications
 - > All the current application intervals
 - > There are no currently planned label changes





- > Technical Registrations
 - » NAA Acid
 - » NAA Sodium Salt
 - » NAD
 - » NAA Ethyl ester
 - > [NAA Potassium Salt]
- AVAMVA[NAA Ammonium Salt]



> End-Use Formulations

K-salt Fruit Fix 200

NAA-K

K-salt Fruit Fix 800

NAA-K

Amid Thin

NAD

Fruitone-N

NAA-Na

Tre-Hold for Citrus etc.

NAA-Et

Tre-Hold Sprout Inhibitor A-112

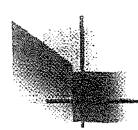
NAA-Et

Prune Smart Sprout Inhibitor

NAA-Et

MAMVAGre-Hold RTU

NAA-Et



> End-Use Formulations (Cont)

Fruit FixTM Conc. 200 NAA-NH4

Fruit FixTM Conc. 800 NAA-NH4

Alco Olive Stop NAA-NH4

Amcotone NAA/NAD

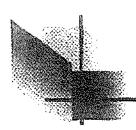
Alco Vit B1 Hormone Conc. NAA

NAA 800 NAA-K

SNAPP-2 NAA-K

SNAPP-8 NAA-K 6





> Target Crops

- > Apples
- > Pears
- > Citrus
- > Olives
- > Prunes
- > Cherries
- » Pomegranates

AWAMVAC > Ornamental Woody Plants

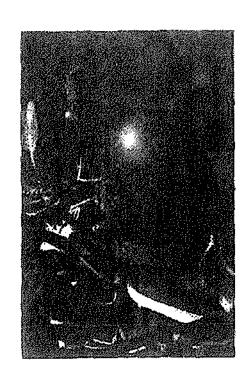
MAMMAC

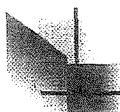
I - Naphthalene Acetic Acid (NAA)

and Derivative Products

Amid-Thing W Fruitone®Z

K-Salt The Fruit Fix The 200 and 8000

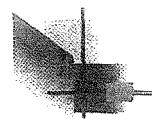




What are Plant Growth Regulators?

- > PGR's are plant hormones Synthesized at one place and transported to act at a different site in plants.
 - > work at extremely low concentrations
 - > act as chemical messengers
- > Five general classes:
 - > Auxins
 - > Cytokinins
 - > Gibberellins
 - > Abscisic acid
 - > Ethylene

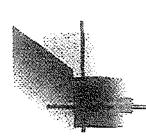




Auxins and NAA

- > Indole 3-acetic acid (IAA) is a natural auxin
- » Naphthalene Acetic Acid (NAA) is a synthetic auxin.
- > Other synthetic auxins include:
 - Indole butyric acid (IBA).
 - > 2,4,5-Trichlorophenoxyacetic acid (2,4,5-T).
- > NAA is the most widely used auxin.

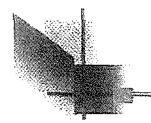




Useful Effects of NAA on Plants - Mode of Action

High auxin content in plants (as when sprayed with NAA), induces the production of ethylene, and causes fruit drop ("thinning").

NAA acts by reducing the transport of reducing sugars to developing fruit in pears AMANDARPIES.



NAA - Mode of Action - 2

- Counteract the effects of abscisic acid (prevents the formation of abscisic layer) as a stop-drop aid.
- > Helps the fruit to stay on tree longer, resulting in larger fruit and harvest date flexibility (up to 2 weeks).

AMVAC'S Family of NAA Products

K+ Potassium Salt

K-Salt[™] Fruit Fix[™] 200 CH₂CHOOH⁺

K-Salt" Fruit Fix" 800

Na⁺ <u>Sodium Salt</u>

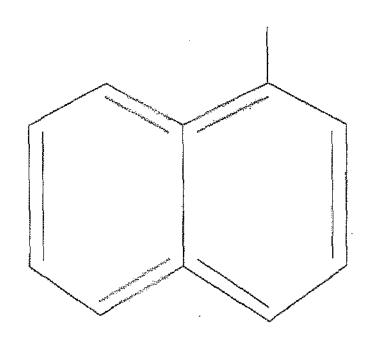
Fruitone® N

NH4+ Ammonium Salt

Fruit Fix" Conc. 200

Fruit Fix Conc. 800

(2)





1-Naphthaleneacetic Acid3

NAA - Database

- > All studies as listed on NPIRS database
- > On-going Toxicology Studies
 - > 80 week Mouse Oncogenicity Study
 - > Rabbit Developmental Study
 - » Rat Developmental Study
 - > In vivo UDS Assay



NAA - Toxicology

- Oral LD50 (Rat):
- Dermal LD50 (Rabbit): >5,000 mg/kg
- > Inhalation LC50 (Rat):
- Eye Irritation:
- LD50 Chronic Feeding: >10,000 mg/kg >(8-day, Mallard duck and quail)

MAMVAC

>10,000 mg/kg

274 mg/kg

Minimal

NAA - Major Uses

hinning for optimum fruit set:

etter than hand thinning because NAA automatically picks the "king" fruit for development.

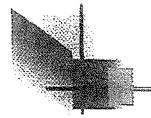
top Drop: Prevents premature drop of fruit

ATAMUMS an aid to delay harvesting. 16

When is NAA used?

- Spring: Used for thinning all varieties of apples, and a small percentage of pears. Chemical thinning is also known to enhance return bloom.
- Summer: Used for enhancing return bloom
- Fall: Used on Red Delicious and AVAIGNATEN Supreme apple trees to prevent 17

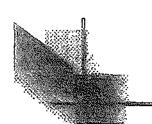
Why is NAA used?



> Market Niche

- > NAA (or similar compounds) are the only alternative to expensive hand thinning
- » NAA can be used between petal fall and 15mm stage of apple development allowing application to take place over a wide time range to cope with different weather conditions
- > NAA can be used in the fall to reduce fruit drop and it is virtually the only option available for this use.





AMVAC'S NAA Products for Thinning - Labels

| | | Crops | | |
|----------------------------|--------|-------|--------|--------|
| Product | Apples | Pears | Citrus | Olives |
| Amid -Thin® | yes | yes | no | no |
| Fruitone® N | yes | yes | no | no |
| K-SaltTM Fruit | yes | yes | yes | yes |
| R ¹ SHR7M9Fruit | yes | yes | yes | yes |



AMVAC'S NAA Products for Stop Drop - Labels

| | | Crops | |
|-----------------------------|--------|-------|------------|
| Product | Apples | Pears | Citrus |
| Amid-Thin® | no | no | no |
| Fruitone® N | yes | yes | no |
| K-SaltTM Fruit FixTM | : yes | yes | no |
| KOSaltTM Fruit FixTM | yes | yes | no |
| 800NH4 Formulations | l no | no | <u>ves</u> |



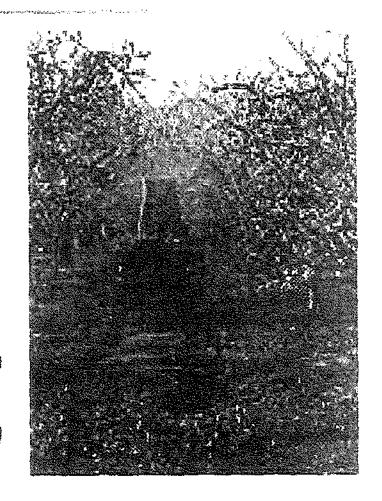
AMVAC'S NAA Products for Return Bloom - Labels

| | Crops | |
|-------------------------|--------|-------|
| Product | Apples | Pears |
| Amid-Thin® | | no |
| Fruitone [®] N | yes | yes |
| K-Saltm Fruit Fixm 200 | no | no |
| K-Saltm Fruit Fixm 800 | no : | No |

APPLICATION DETAILS

Apple Thinning

- > Amid-Thine
- > Fruitone® N
- > K-Saltm Fruit Fixm 200
- > K-Salt^m Fruit Fix^m 800



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- > All applications are made by air-blast sprayers
- > Applications are designed to wet leaves to the point of drip
- > Sprays are directed to the upper 2/3 of the tree



Factors Affecting Thinning

- > Leaf temperature, leaf age, leaf surface, spray volume and droplet size.
- > Weather conditions such as: ambient temperature, relative humidity and wind speed.
- > Tree health, pH of spray solution, adjuvants.





- > Rate range is from 15 to 50 ppm and can be applied at petal fall or up to 14 to 18 days after full bloom.
- Do not apply Amid-Thin® W to Red Delicious apples in the Pacific Northwestern states or pygmy fruit may develop (Use Fruitone® N).



Amid-Thin⁹ W Recommendations for Pears

- > For thinning of Bartlett and Bosc pears
- apply at a rate of 10 to 50 ppm at petal fall or within 5 to 7 days after petal fall
- > Use up to 400 gallons

 per acre

 AVAIVAC



Fruitone® N on Apples - Use Directions for Thinning

- > Use range is from 2 to 20 ppm- the higher concentrations should be restricted to vigorous trees with high fruit set potential.
- Application window is from petal fall to 21 days after full bloom.
- > Fruitone® N should not be used on early season varieties such as Oldenburg, Early Williams etc.
- Preferred application temperature is between 70 to 75 deg F. Avoid applications < 60 deg F and >80 deg F.



Fruitone[®] N - Use Rates for Thinning in Bartlett Pears (Oregon, 24c SLN)

| Gallons Per Acre | <u> </u> | | 300 | 400 | 500 |
|------------------|----------|--------|------|------|-----|
| Rate (ppm) | | Fruito | ne N | (oz) | |
| 12.5 | 15 | 20 | 25 | | |
| 15.0 | 18 | 24 | 30 | | |

Add surfactant at the rate of 2/3 to 1.0 pint surfactant per 100 gallons of water. Spray 15 to 28 days after full bloom.





- > Rate varies from 2 to 20 ppm depending on variety, temperature and vigor of trees
- > Timing Can be used from petal fall to 30 days after petal fall
- > Most effective when king fruitlets are between 5 to 10 mm diameter
- > Wetting agent can be added for maximum efficacy



K-Salt" Fruit Fix" 200 or 800 for Thinning Pears

Can be used on Bartlett, Bosc an Comice varieties.

Use at the rate of 10 to 15 ppm.

- 2.4 oz K-SaltTM Fruit FixTM 200 in 100 gallons of water gives 10 ppm.
- -0.6 oz of K-Salt Fruit Fix 800 in 100 gallons of water gives 10 ppm
- F or above 80 deg F.



- > Spray when young fruits are 1/8 to 3/16 inch in diameter, or 12 to 18 days after full bloom.
- > Apply 28.8 oz product in combination with a wetting agent in adequate quantity of water.
- > Rule of Thumb: Increase concentration by 10 ppm for each additional day after full bloom.



K-Salt™ Fruit Fix™ 200 or 800 for Thinning Citrus

- > Spray at 100 to 500 ppm
- Severe over thinning can occurduring hot, dry weather.
- > Spray when fruits are 5 to 20 mm in diameter and during "June drop".
- Do not make more than one application per ANACPHI is 150 days.

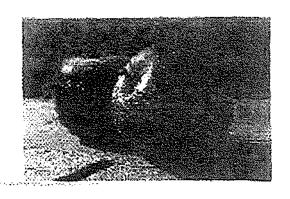
and 800 for Stop Orop Use in Apples Fruitone N and K Salt Fruit Fix 200 and Pears





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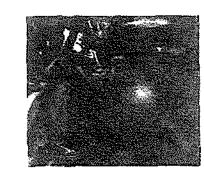




- > Fruitone® Nusually becomes effective 2 days post treatment when weather is warm.
- > For best efficacy apply Fruitone® N when temperatures are >70 deg F.
- > Spray entire tree wetting all foliage and fruit.
- » Rates range from 5 to 20 ppm depending on variety



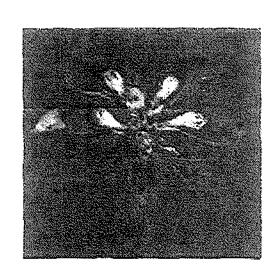
K-Salt Fruit Fix 200 or 800 as a Stop Drop Aid



- > Can be used for both apples and pears.
- Apply 7 to 14 days prior to harvest. Do not exceed 2 applications for this use per season.
- > Use at the rate of 16 to 32 oz (apples) or 8 to 16 oz K-Salt" Fruit Fix" 200 (pears) in sufficient water to ensure good coverage
- > Use K-Salt 800 at ½ rate of K-Salt 200.
- Seasonal maximum is 50 grams NAA per acre.
- Use a maximum of 16 oz per acre of K-Salt 200 per season on ANNIA Cars to avoid premature ripening.



- > Can be used at the rate of 25 to 50 grams per acre
 - 5 to 20 ppm final spray solution, thorough coverage.
 - > seasonal maximum is 50 grams per acre.
- Mid summer "loading up" with up to 4 applications of NAA provides the benefit of stop drop as well as return bloom the following spring.





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- > ไกษยย์เรมีอส
- Technical Degistrations
- i End-Use Forwoldtians
 - Available Date
- Use Patterns

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 - > There are no correstly planted lebel elemen

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AMVAC GAZHILAN. GARRARAYZAN MAA AND RELATED COMMUNDS

> Technical Registrations

- > NAA Acid
- » NAA Solčum Selt
- > NAD
- : NAA Ethyl ester
- > (MAA Pokensiga Schi)
- IMAA Americakaa Solo]

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MAVAÇ ÖNEMLEML CORFGRATZON MAA ASID BELATED KOMPONDO

> End-Usz Formulations

(5-7-1) (Both Feb 120) 1376-0 County (five size five size) 12AA.II MASS > Amid This RAMO ್ (ಕೇವನಿಯಾನಿ) r Westeld for Estemate. 经政体证金 to Translated Springs Spillers of Audio (430-0) o Presidence Section of Course Michigan 809.8-50 STREET, STREET MALES SE

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> End-Use Fermulations (Cent)

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MANNE EXECUTER CORPORATION RUM MAIO RELATED COMPOUNDS

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 - и-Ретодиктакыз
 - >Omercuial Wordy Media

NAMVAC



I-Nephhalose Acolle Aeld (MIA) esd Berkotke Produce

Assid-Then? W Frencaro N K-Sali Truit Fix 200 600 bns



MANUAC



Whee are Flant Crowll Regulation ?

- PRIVe era plant horasans Synthodical et ena plass and transperted to est at a different into in plants.
 - to epicyl tak sughymnofy fina emocuolysmilina in med naethomike Astronionyasa
- 14 Managanizal efections
 - Dr Februar

 - D Libras D Cyteldriae D Cliffordlise D Mordile edd D Ethyloro

Mamvac



Accing and NAA

- > Indel: 2-esotic add (LAA) to anchoral egon:
- Maglidialena Applio Acid (MAA) in elejathotic cuida.
- O fict a publicate negation holights
 - 1.111 hayste cal 3 (200).
 - or the UNASSET Textifue sequenciate and Constitute
- > NAA to the most widely used ceals.

*M*amvac



Usafed Efficers of NAA on Menns - Merio of desim

- > High œxin content in glants (es when sprayed with NAA), induces the production of chiplene, and causes fruit throp ("thinning").
- : WAA cots by redecing the treasurer of reducing sugars to discloping finit in providend eppiss.

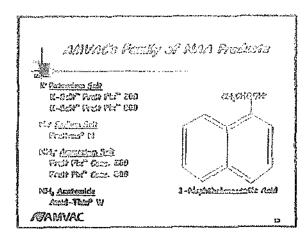
FUAMVAC

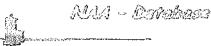


NAA - Modo of Aeston - 2

- » Counteract the office to of absolute cold (prevented the formation of educateic layer) as a shop-drop edd.
 - Voltes the fresh to stay on their larger, receiving in larger field and harvers date flowfalls for to 2 cm shell.
- Countries disconsis becoming to come temps each ex ್ಯಾಸಿಯಲಾಗೆ ಕ್ಷಿಯಾಗಿ
 - Engineer Tradeurs (Con. # 2020, y 102 \$200 along presents)

MAMMAE

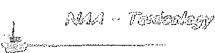




- All studies as listed on NYTRS database
- > Cargeing Texteology Studies
 - > GB work Alterna Change Later (See L)
 - State business of the Carl
 - #057 browingschuld S961; #19 the U05 Array
 - 1 (0-e 1 cm) 4:16

*A*VAMVAC

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- r Ord Li)_{ca} (Ref):
- >10,000 ay/ag
- : Comed Liber (Middle):
- 25,689 ug/kg
- > Inhalawan (LC_{CO} (fins):
- 274 (25A2)
- > Eys Irritation:
- Maksoi
- 18029 Obrania Perdings
 19-12 detention en en en
- MORE BOD, OR

/TAMVAC

1-5

NAA - Major Uses

- i- Unioning for opposition fruit con-
 - > bester that bend thinky basics this established plain the 'they' frest for dividences.
- Otop Brogs Provints produktracing of finitions, also as aid to doing horocaling.
 - : Fronting wifferen inside by each inducted fresh class.
- Determ Blassa Premaries Floriering and provides condictem blassa year effor year.
 - > Provento obernate lesering.

*F*VAMVAC

15



When is NAA used?

- Spring: Used for thirding oil varieties of region, and a small percentage of pours. Chemical thirding to elso known to otherwo nerver blocks.
- > Summer: Used for enhancing return bloom
- : Polk Urad og flad Dalpstona og á Colling - Trjulans egyfarfollarfolprindað græsforum af Collip
- Spread inhibition: Applied office a pounting out to provide police contains from documenting

MAMMAC

.r

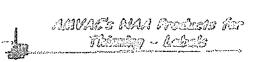


CHIP O MAIN WOOM

- > Market Niche
 - NAA (or dailer companie) are the only of remains to expensive that this are
 - PCBA consistent mapping Classes Silverson, police of Silverson, police of Silverson and Constitution Constitution Constitution Constitution Constitution Constitution Constitution (Constitution)
 - වර්වේ පසු මහ පහල් වැනිපත්ත්ව මහ පත්තය සහ පස්තු පස්තුව විය වෙරපත්තු විය පර්තු පත්තය සහ වියව සහ විවිත පත්තය.

Nammac

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| Product | Apples | Peers | Clirus | Olives |
|----------------------|--------|-------|--------|--------|
| Assistant | 1750 | Apa | 227 | 89 |
| Trainer H | hen. | yes | F23 | (ta) |
| - Company 12 1 200 | 320 | уся | was] | ha |
| Company Francisco | ¥29 | 1520 | 1234 £ | yes |

| amuct a | | | 807 S |
|-----------------------|---------------|---------------|------------|
| Ð | TP - Le | ahak | |
| | | | |
| Day. | | | |
| | | Over | |
| | | | |
| Produse | Aratur | Pecen | क्षेत्रस्य |
| Product Audio West | (Ayatar Co | Persona no | ರಾ ಕ |
| | | | |

MANIVAC

E Com Projetin 180

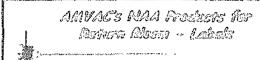
PMARK Research

Sca

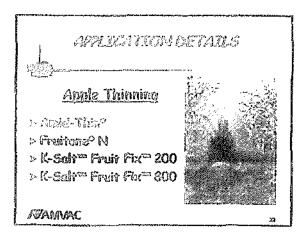
782

123

123



| | ಟಿ ಶ್ | # J | |
|------------------------|--------------|-------|--|
| Product | Applica | Pozro | |
| Amid-Visto | 17.9 | | |
| Preitens N | 1/20 | yes | |
| K-Sallo-Fruit Flor 200 | 022 | ino | |
| K-Seito Freit Flao CCD | no | No | |





MAMVAC

*IT*AMVAC

AFRICATION DETAILS

- > All explications are made by air-blast sproyers
- Applications are Conjugated to our function the point of Cop
- > Sarays are directed to the upper 2/3 of the tree

*FT*AMVAC



Persons Affecting Thinning

- > Loof temperature, loof egs, loof curface, spray values and droplet size.
- > Weather conditions such as: ambient temperature, relative luncidity and wind weed.
- to Mara health, gold of Huray colods a, a if no size.
- > Nec valety

/VAMVAC



Amid-Thid VV Recommendations for Apples

- Rate range is from 15 to 50 ppin and can be applied at petal fall or up to 14 to 18 days after full bloom.
- » Do not apply Amid-Thin^o W to Red Delicious apples in the Pacific Northwestern states or pygmy fruit may develop (Use Fruitane^a N).

MAMVAC

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Amid-Thir^o W Recommendations for Poors

- For thirming of Bartlett and Base peurs
- > apply at a rate of 10 to 50 ppm at petal fall or within 5 to 7 days after petal fall
- Use up to 400 gallons per acre



ATAMVAC



Fruitous^o N on Apples - Usa Directions for Thinking

- Use respects from 2 to 20 ppm-the bights acceptable of death) be respirated to eigenous iversetablish fruit set to be distill.
- Application receive technological fedicions of expensive field block.
- Fruiture² bishould not be used as early escasor verteries such as Olicobery, Early Willemann.
- » Preferred application respectance is between 70 to 78 day F. Assid applications 4 60 day F and 450 day F.

MAMVAC

13

Fruitons? IV - Use Rotes for Thliening in Bortlett Fears (Oregon, 24c SEM)

| Gallones Per Aona> | Aço | 400 | 500 | • |
|--------------------|-----|----------|------|---|
| Raha (ppna) | He | idoro (1 | (nz) | _ |
| 125 | 115 | Z0 | 25 | |
| 15.0 | 18 | 24 | 30 | |

Add curfection at the rate of 2/3 to 1,0 girl confeatual per 100 gallone of mater, 5 jovey 15 to 25 days efter full blocar.

MAMVAC



K-Salt Fruit Fix 200 or 600 for Thinning Apples

- Rate varies from 2 to 20 ppm depending on variety, temperature and vigor of trees
- Throng Cur be need from petal fell to 30 days after petal fell
- Mast effective when hing fruitless are beinges to to 10 mm elemeter
- > Werming again sea boadded for mortulas of flower
- > Can be inhead with cortraryl

MAMYAC

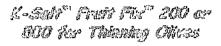
....e

K-Self Fruit Fix" 200 er 800 for Thiming Pears

- Con be used en Bartlett, Base and Camica varieties.
- s that at the rate of 10 to 15 pan.
 - > 20 ok 15-5ch from FRE 200 in 100
 - gillow of nature from 10 plan.
 - ২ -উক্ত কেন্দ্ৰেই চিনিউন্না ক্ৰিন্দ্ৰেই ইন্দ্ৰেই ইন্দ্ৰেই কৰিছে 100 ব্ৰোচনত কৰিছে লাজকা ক্ৰিন্দ্ৰ 10 কৃচ্চন
- Do not make applications below 60 deg F or above 80 deg F.
- Some Inconsistency seen with Borders variety.

MAMMAC

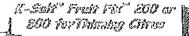
)

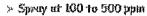


- Spray when young fruits are 1/8 to 3/16 inch in diameter, or 12 to 18 days after full bloom.
- » Apply 2018 or product in continuation with a weiting agent in adequate quantity of voter.
- Duls of Thank Increase concentration by 10 ppm for each additional day after full bloom.

MAMVAC

'n

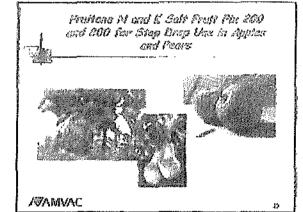




- Severe over thinning can occur during kert, dry context.
- Spray when fruits are 5 to 20 mm in diameter and during "June drop".
- Do not hade more than one application per senson. PML is 150 days.

MANWAC

TIY





Fruiters M on Applied and Award - Step Drop



- Fruitone" Nacually becames of feeting 2 days post treatment when weather to worm.
- » For best efficacy apply Fruitone[®] Muchen temperatures are >70 deg F.
- > Spray entire tree welting all folioge and fruit.
- Rates range from 5 to 20 ppm depending on variety

ETAMVAC

..

K-Sali^m Fruit Flui^m 200 or **,900** os a 5top Orto Ald



- » On he used for both captes and pears.
- Apply 7 to 14 days prior to horsest. Do not exceed 2 applications for this ten per source.
- Minimen Administratif has no SE on fugation) or their has no happing from Mills (princip) in individual hashes to dimense good amorting.
- → Max K-Sett 600 of £ rate of K-Selt 200.
- a. Summed marrial or to US greate MAG per sur-
- Use a resolution of the experience of Gebate 200 per resolution forther passes to arisel primariene equations.

AMAMWAC

-

Use of Fruitms^o IV to Apples and Poors for Raturn Diom

- Gun be tiped at the rate of 25 to 50 grants per acre
 - > 13 to 20 pper field spray minima, thereof.
 - > cocomó moditiva to 50 grand par cara.
- Mid cummer "loading up" with up to 4 applications of NAA procides the beautiful ut utop drop on call as return bloom the following oping.





34

Amvac Company Representatives for NAA SMART Meeting April 9, 2003

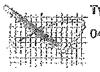
lan Chart Vice-President, Director of Regulatory Affairs

Kyle Coleman NAA Commercial Marketing

John Immaruju, Phd Manager International Product Development

Darryl Brook Product Manager

Ann Manley Director of Toxicology



Tylor Lane 2 04/02/03 05:48 PM To: Abdallah Khasawinah/DC/USEPA/US@EPA, Allan Halvorson/DC/USEPA/US@EPA, Allan Vaughan/DC/USEPA/US@EPA, Arthur Grube/DC/USEPA/US@EPA, Cynthla Doucoure/DC/USEPA/US@EPA, Dave Jaquith/DC/USEPA/US@EPA, Dennis McNeilly/DC/USEPA/US@EPA, Gary Otakie/DC/USEPA/US@EPA, Hoyt Jemerson, John Bazuin/DC/USEPA/US@EPA, Mah Shemim/DC/USEPA/US@EPA, Michael Goodis/DC/USEPA/US@EPA, Mojmir Mazur/DC/USEPA/US@EPA, Nell Anderson/DC/USEPA/US@EPA, Nicole Mosz/DC/USEPA/US@EPA, Refeel Prieto/DC/USEPA/US@EPA, Ray Kent/DC/USEPA/US@EPA, Richard Dumas/DC/USEPA/US@EPA, Richard Keigwin/DC/USEPA/US@EPA, Roger Clark/DC/USEPA/US@EPA, Steve Jarboe/DC/USEPA/US@EPA, Timothy Leighton/DC/USEPA/US@EPA, James Felkel/DC/USEPA/US@EPA

CC

Subject: NAA: Amvac Representatives[]



Chemical Review Manager
Office of Pesticide Programs
Special Review and Reregistration Division

MC: 7508C

Phone #: (703) 305-2737 Fax #: (703) 308-8005



Tyler Lano

04/09/03 11:08 AM

To: John Baxuin/DC/USEPA/US@EPA

cc:

Subject: Re: NAA SMART meeting (R)

John-

The meeting was changed to room 1103. I had updated the room change on the meeting announcement, but perhaps this was not transmitted to all the participants. Dennis McNeilly was in attendance from RD and I will be sending out the minutes soon. I apologize for the mix up- Tyler

Chemical Review Manager Office of Pesticide Programs Special Review and Reregistration Division

MC: 7508C

Phone #: (703) 305-2737 Fax #: (703) 308-8005

John Bazuin



John Bazuin

04/09/03 09:13 AM

To: Tyler Lane/DC/USEPA/US@EPA

cc: Richard Keigwin/DC/USEPA/US@EPA, Dennis

McNeilly/DC/USEPA/US@EPA

Subject: NAA SMART meeting

Tyler,

I attempted to find the meeting but was unsuccessful. Nobody was in Room 604 (Think Room) and none of the other conference rooms on the 6th floor, that I could find, were the correct ones, either. Someone else was also walking around the area, trying to find the meeting. I think he was also unsuccessful.

John Bazuin



John Bezuin

04/09/03 09:09 AM

To: Tyler Lane/DC/USEPA/US

cc: Richard Keigwin/DC/USEPA/US, Donnis McNoiNy/DC/USEPA/US

ec:

Subject: NAA SMART meeting

Tyler,

I attempted to find the meeting but was unsuccessful. Nobody was in Room 604 (Think Room) and none of the other conference rooms on the 6th floor, that I could find, were the correct ones, either. Someone else was also walking around the area, trying to find the meeting. I think he was also unsuccessful.

John Bazuin



Rafael Prieto 04/03/03 05:28 PM

To: Tyler Lane/DC/USEPA/US@EPA, John

Bazuin/DC/USEPA/US@EPA, Allen

Vaughan/DC/USEPA/US@EPA, Ray Kent/DC/USEPA/US@EPA,

Nicole Mosz/DC/USEPA/US@EPA, Roger Clark/DC/USEPA/US@EPA, Abdallah

Khasawinah/DC/USEPA/US@EPA, Gary

Otakie/DC/USEPA/US@EPA, Timothy

Leighton/DC/USEPA/US@EPA, Jose

Melendez/DC/USEPA/US@EPA

cc: Sid Abel/DC/USEPA/US@EPA, Tom Bailey/DC/USEPA/US@EPA,

Betsy Behl/DC/USEPA/US@EPA, Donna Davis/DC/USEPA/US@EPA, Marion

Johnson/DC/USEPA/US@EPA, Amet

Jones/DC/USEPA/US@EPA, Richard

Keigwin/DC/USEPA/US@EPA, Ray Kent/DC/USEPA/US@EPA,

Susan Lawrence/DC/USEPA/US@EPA, Meredith

Laws/DC/USEPA/US@EPA, Arnold Layne/DC/USEPA/US@EPA,

Susan Lewis/DC/USEPA/US@EPA, Deborah

McCall/DC/USEPA/US@EPA, Michael

Mcdavit/DC/USEPA/US@EPA, Robert

Mchally/DC/USEPA/US@EPA, Michael

Metzger/DC/USEPA/US@EPA, Kathy Monk/DC/USEPA/US@EPA,

Margaret Rice/DC/USEPA/US@EPA, Doug

Sellers/DC/USEPA/US@EPA, Betty

Shackleford/DC/USEPA/US@EPA, Mah

Shamim/DC/USEPA/US@EPA, Dana Spatz/DC/USEPA/US@EPA,

Thomas Steeger/DC/USEPA/US@EPA, Donald

Stubbs/DC/USEPA/US@EPA, Pauline Wagner/DC/USEPA/US@EPA, David

Widawsky/DC/USEPA/US@EPA, OPP BEAD Reregistration Team,

Michael Goodis/DC/USEPA/US@EPA, Anne

Overstreet/DC/USEPA/US@EPA, Cynthia

Giles-Parker/DC/USEPA/US@EPA

Subject: Use Profiles: NAA (CASE 0379)

Now with the Use Profiles! ==> 🖺

Click on each of the four (4) tabs to access the information inside.

| Chemical Number | Chemical Name | Status |
|-----------------|---|-----------|
| 056001 | I-Naphthaleneacetamide (NAD) | Completed |
| 056002 | 1-Naphthaleneacetic acid (NAA) | Completed |
| 056003 | i-Napisthaloneacetic acid, potassium salt | Completed |
| 056004 | 1-Naphthaleneacetic acid, ammonium sait | Completed |
| 056007 | I-Naphthaleneacetic acid, sodium salt | Completed |
| 056008 | l-Naphthalencatelic acid, ciliyl ester | Completed |

Document Links to the following Label Data reports of NAA Case (Number 0379) are attached. Click once on the Document Links to view the database record. To print each report, LAUNCH the attachment in wordperfect or Lotus 2-2-3, as appropriate. You can also DETACH the files and then print from the appropriate program.

NOTE: You should not attempt to print directly from Lotus Notes, since the attachments will not print correctly.

LABEL DATA (LUIS) REPORTS Link Report Name Olvision Link Report Name Divisio Table AZ New! SRRD Appendix A Spreadsheet HED RED Use Profile HED I Table A3 Newl HED Label Data Spreadsheet RED Usage Data (% crop treated, etc)** MED Label Issues EFED Env. Fate & Effects Spreadsheet Label Tracking (changes since last Full General Chemical Report EFED/HED update) Link to list of OPP Reregistration team Kall []]. ** Please contact the OPP BEAD Reregistration Team by e-mail, if you need usage Information (like percent crop treated) and a meeting will be setup to address your specific usage needs. Vocabularies Used on Spreadsheet Reports Code Link Vocabulary Type G Geographic Vocabulary Crop/Site Limitations C H **Pre-harvest Limitations** S Pre-slaughter Limitations Feeding and Grazing Limitations INSTRUCTIONS - To complete this form Choose 'Reply with History' from the Icon bar, Delete the choice that you don't want when answering a Yes/No question, Move your cursor to the line below the question to type in a response. · Click the 'Send' button from the icon bar when finished. 1. What is your Division? Please type your answer here: 2. What is your Branch? Please type your answer here: 3. Did you receive the reports in a timely manner? Yes 4. Were the data reports helpful in your preliminary review of this chemical (and its associated registrations)? Yes 4a. If your answer is No, how could the reports be improved to better help you in your review of this chemical? Please type your answer here: 5. Were the reports legible? 5a. If your answer Is No, please explain. Please type your answer here:

6. Do you have any additional comments or cuestions?

Please type your answer here:

Satisfied with your responses? If so, please dick the 'Send' button from the icon bar to submit this form. Thank you.



Tylor Lane | 04/02/03 10:48 AM To: Abdallah Khanawinah/DC/USEPA/US@EPA, Alan Haivorson/DC/USEPA/US@EPA, Allan Vaughan/DC/USEPA/US@EPA, Arthur Grube/DC/USEPA/US@EPA, Cynthia Doucoure/DC/USEPA/US@EPA, Dave Jaquith/DC/USEPA/US@EPA, Dannis McNeilly/DC/USEPA/US@EPA, Gary Otakio/DC/USEPA/US@EPA, John Bazuin/DC/USEPA/US@EPA, Michael Goodis/DC/USEPA/US@EPA, Michael Goodis/DC/USEPA/US@EPA, Mojmir Mazur/DC/USEPA/US@EPA, Neil Anderson/DC/USEPA/US@EPA, Nicola Mosz/DC/USEPA/US@EPA, Rafael Prieto/DC/USEPA/US@EPA, Ray Kont/DC/USEPA/US@EPA, Richard Durnos/DC/USEPA/US@EPA, Richard Keigwin/DC/USEPA/US@EPA, Roger Clark/DC/USEPA/US@EPA, Stevo Jarbos/DC/USEPA/US@EPA, Timothy Leighton/DC/USEPA/US@EPA, Jose Malendez/DC/USEPA/US@EPA

CC

Subject: NAA Reregistration

All,

Attached you will find a contact list for the MAA reregistration team. If any adjustments need to be made to this list, please contact me. Also, I've sent a rough draft of a Guideline Status Table that I have been updating from a variety of sources to keep track of the status of any required studies. If any of you have updates to this list, please send them to me. I have sent a status report to the registrant which I will use to cross-check against our databases and update as necessary. If any of you have further questions, feel free to contact me and I look forward to seeing you on the 9th.

Tyler

Chemical Review Manager
Office of Pesticide Programs
Special Review and Reregistration Division

MC: 7508C

Phone #: (703) 305-2737 Fax #: (703) 308-8005

Į.

NAA Reregistration Team Guideline Status 3-25-03.

Napthaleneacetic Acid (NAA) Reregistration Team 056001, 056002, 056003, 056004, 056007, 056008

| RD | Richard Keigwin | 305-7618 | (Branch Chief) |
|-----------|----------------------|------------|---------------------------|
| | John Bazuin | 305-7381 | (Fungicides) |
| ********* | on TV . | | 60 1 04 1 6 |
| HED | | 305-7379 | (Branch Chief) |
| | Abdallah Khasawinal | ı 305-1226 | (Risk Assessor) |
| | Gary Otakie | 305-6991 | (Chemist) |
| | Tim Leighton 305-74 | 31 (ORE) | |
| efed | Mah Shamim | 305-5025 | (Brench Chief) |
| | Allen Vaughen | 308-8327 | (Team Leader) |
| | José Meléndez | 305-7495 | (Chemist) |
| | | , | (, |
| SRRD | Michael Goodis | 308-8157 | (Branch Chief) |
| | Neil Anderson 308-81 | 37 (Team | Leader) |
| | Tyler Lane | 305-2737 | (Chemical Review Manager) |
| READ | Steve Jarboe | 308-8105 | (Team Leader) |
| | Nicole Mosz, | 308-7076 | (Biologist) |
| | Roger Clark | 308-8099 | (Usage) |
| | Alan Halvorson | 308-8070 | , , |
| | | | (Economist/QUA) |
| | Mojmir Mazur | 305-5975 | (Usage) |
| | Rafael Prieto | 308-8152 | (Labels) |
| USDA | Ted Rogers | 720-3846 | |

Mentioned unspecifically in Registration Standard, but see Established Cited as See Established Standard

| Guideline Number | Description . | 056001 amide | 056002 acid | 056003 K salt | 056004 NH ₄ san | 056607 Na sak | os6008 Ethyl |
|---------------------------------------|--|------------------------|------------------------|------------------|-------------------------------|------------------|------------------------|
| | Beginning material & manufacturing process | | No decision | | | | |
| | Discussion of impurities | | No decision | | | | |
| | Preliminary analysis | | No decision | | | | |
| | Color | | No decision | | | | |
| e e e e e e e e e e e e e e e e e e e | Physical state | | No decision | | | | |
| | Odor | | No decision | | | | |
| | Melting point | | No decision | | | | |
| | Boiling point | | No decision | | | | |
| | Density | | No decision | | | | |
| | Solubility | | No decision | | | | |
| | Vapor pressure | | No decision | | | | |
| | Dissociation constant | | No decision | | | | |
| | Oct/water partition coefficient | | No decision | | | | |
| | PH | 8 HX 51 | No decision | | | | |
| | Stability | | No decisioa | | | | |
| -2(a) | Acute avian distary quail | Acceptable 42484201 | | | | | Acceptable 42584202 |
| | Fish toxicity bluegill | | Acceptable 00082527 | | | | Acceptable 42498101 |
| 72-4(b) | Fish toxicity rainbow troat | | Acceptable 00082528 | | | : | |
| (2200) | Invertebrate toxicity | | Acceptable 00082526 | | | | ln review 42470801 |
| 72/200 | Invertebrate toxicity-TEP | |] | | | | |
| 77.71(8) | Estuarine/marine toxicity fish | | | | | | _ |
| 溢-3(6) | Estuarine/marine texticity mollusk | | | | | | |
| 98200 | Estuarine/marine toxicity shrimp | | | | | | |
| 72-3(0) | Estuarine/marine toxicity fish-TEP | ,,,,, | | | | | |

| Guideline Number | Description | 056001 amide | 056002 acid | 056003 K salt | 056004 NH ₄ salt | 056007 Na salt | 056008 Ethyl |
|---------------------|---|------------------------|---------------------------------------|----------------------------|--------------------------------|------------------------|------------------------|
| 72-3(e) | Estuarine/marine toxicity mollusk- TEP | | | | | | |
| 72-3(f) | Estuarine/marine toxicity shrimp- TEP | | | | | | |
| 72-4(a) | Early life stage fish | | | | | | |
| 72-4(b) | Life cycle invertebrate | | | | | | |
| 72-5 | Life cycle fish | | | | | | |
| 72-6 | Aquatic org. accumulation | | | | | | |
| 72-7(a) | Simulated field- aquatic organisms | | | | | | |
| 72-7(b) | Actual field- aquatic organisms | | | | | | |
| -1 | Acute Oral Toxicity- Rat | In Review 43495901 | Acceptable 00103128 | | | | |
| 81-2 | Acute dermal toxicity rabbit/rat | In Review 43495902 | Acceptable 00103129 | | | | |
| 81-3 | Acute inhalation toxicity rat | In Review 43495903 | Waived- not documented 00122676 | | | | |
| 81-4 | Primary eye irritation rabbit | In Review 43495904 | Acceptable 00103127 | | Acceptable 00100515 | | |
| -5 | Primary dermal irritation | Acceptable 00103220 | Acceptable 00103127 | | | | Acceptable 00103218 |
| 81-6 | Dermal sensitization | In Review 43495905 | Acceptable 00153217 | | | | In review 43914901 |
| 82-1(a) | 90-day feeding rodent | In Review 43896001 | | | | | In review 43896002 |
| 82-1(b) | 90-day feeding nonrodent | In Review 43895901 | | | | | In review 43914901 |
| 82-2 | 21-day dermal rabbit/rat | In Review 43581001 | Waived-will use Na salt | Waived-will use Na salt | Waived-will use Na salt | Acceptable 43134701 | In review 43581002 |

| Guideline Number | Description | 056001 amide | 056002 acid | 056003 K salt | 056004 NH ₄ salt | 056007 Na salt | 056008 Ethyl |
|---------------------|-------------------------------------|------------------------|------------------------------------|--|------------------------------------|-----------------------|------------------------|
| 83-1(a) | Chronic toxicity- rodent | | Waived-will use Na salt | Waived-will use Na salt | Waived-will use Na salt | In review 44157501 | |
| 83-1(b) | Chronic toxicity- nonrodent | | In Review- will use Na salt | Waived-will use Na salt | Waived-will use Na salt | In review 43744201 | |
| 83-2(a) | Oncogenicity | | Waived-will use Na salt | Waived-will use Na salt | Waived-will use Na salt | In review 44157501 | |
| 83-3(b) | Teratogenicity rabbit | | Acceptable 00137821 00137822 | | | | |
| 83-4 | 2 generation reproduction | | Waived-will use Na salt | Waived-will use Na salt | Waived-will use Na salt | In review 43796301 | |
| | | | | | | | |
| 64-2(a) | Gene mutation ames | In Review 43581006 | | | | | In review 43580201 |
| 84-2(b) | Structural chromosome aberration | In Review 43581005 | | | | | In review 43580202 |
| 84-4 | Other genotoxic effects | In Review 43580202 | | | | | In review 43580201 |
| 85-1 | General metabolism | In Review 43963301 | | | | | In review 43961701 |
| 122-1(a) | Seedling germination/emergence | Waived | Waived | Acceptable 43837401+ 42584203 | In review 43803201 | Waived | Waived- Minor use |
| 122-1(b) | Vegetative Vigor | Waived | Waived | Acceptable 43168101 43141101 42564202 | Acceptable 43168301 42564201 | Waived | Waived- Minor use |
| 2-2 | Aquatic plant growth | Waived | Waived | Acceptable 42582201 42582202 | Acceptable 42582204 42582203 | Waived | Waived- Minor use |
| 123-1(a) | Seed germination/seedling emergence | | | Acceptable 43837401+ 42584203 | | | |
| 161-1 | Hydrolysis | Acceptable 00129382 | | | | | Acceptable 00129382 |
| 161-2 | Photodegredation- water | | | | | | |
| 161-3 | Photodegredation- soil | | | | | | |
| 161-4 | Photodegredation- air | | | | | | |
| 162-1 | Aerobic soil metabolism | | | | | | |
| 162-3 | Anaerobic soil metabolism | 1 | 7 | | | | |
| 162-4 | Aerobic aquatic metabolism | | | | | | |

| Guideline Number | Description | 056001 amide | 056002 acid | 056003 K salt | 056004 NH ₄ salt | 056007 Na salt | 056008 Ethyl |
|---------------------|--------------------------------|-----------------------------------|-----------------------------------|-----------------------|--------------------------------|-----------------------|-----------------------------------|
| 163-1 | Leaching/adsorption/desorption | | | | | | |
| 163-2 | Volatility- lab | | | | | | |
| 163-3 | Volatility- field | | | | | | |
| 171-4(a) | Nature of residue- pl | In review 44184401 43958501 | In review 55190501 43948501 | In review 44190501 | No decision | No decision | In review 44190501 43958501 |
| 171-4(b) | Nature of residue- li | Waiver request | In review 43692301 | No decision | No decision | In review 43692301 | Waiver request |
| 171-4(e) | Storage stability | Waiver request | No decision | No decision | No decision | No decision | Waiver request |
| 171-4(k) | Apple | Waiver request | No decision | No decision | No decision | No decision | Waiver request |
| 1-4(k) | Olive | Waiver request | No decision | No decision | No decision | No decision | Waiver request |
| 171-4(k) | Orange | Waiver request | No decision | No decision | No decision | No decision | Waiver request |
| 171-4(k) | Pear | Waiver request | No decision | No decision | No decision | No decision | Waiver request |
| 171-4(k) | Tangerine | Waiver request | No decision | No decision | No decision | No decision | Waiver request |
| 171-4(1) | Apple | Waiver request | No decision | No decision | No decision | No decision | Waiver request |
| 171-4(I) | Citrus group | Waiver request | No decision | No decision | No decision | No decision | Waiver request |
| 171-4(I) | Olive | Waiver request | No decision | No decision | No decision | No decision | Waiver request |
| 1 | Estimation of dermal exposure | | | | Reserved | | |



Tyles Lano

To: John Bazuin/DC/USEPA/US@EPA

cc:

03/31/03 11:42 AM Subject: Re: NAA Weiver Info@

thanks. i'll stop by and pick it up.

Chemical Review Manager Office of Pesticide Programs

Special Review and Reregistration Division

MC: 7508C

Phone #: (703) 305-2737 Fax #: (703) 308-8005

John Bazuin



John Bazuin

To: Tyler Lane/DC/USEPA/US@EPA

co:

09/31/03 11:21 AM

Subject: Re: NAA Waiver Info@

Tyler,

The only useful acotox, into I've found in my binders is a data listing (with MRID Number (s), or response type, or study progress, or submission status) from Amvac concerning an NAA data calt-in in 1990. I have a copy for you. This listing shows submission of Acute Bobwhite (71-2(a)), Bluegill Tox. (72-1(a)), invertebrate Tox. (72-2(a), and Tier I and II plant growth, seed germination, and vegetative vigor (122-2, 123-1(a), 123-1(b), and)123-2.

John Bazuin

<<<<0>>>>

Tylor Lane



Tyler Lano

To: John Bazuin/DC/USEPA/US@EPA

03/31/03 08:19 AM

Subject: Ro: NAA Waiver Info

john-

I"ve invited rick and dennis and will be meeting with EFED this afternoon to discuss the ecotox database. thanks for the input and let me know if you come across anything further-tyler

Chemical Review Manager Office of Pesticide Programs

Special Review and Reregistration Division

MC: 7508C

Phone #: (703) 305-2737 Fax #: (703) 308-8005

John Bazuln



John Bazum

To: Tylor Lane/DC/USEPA/US@EPA



03/28/03 04:44 PM

co:

Subject: Re: NAA Waiver Info

Tylor,

I suspect that the reasons behind low ectox, deta may be lost in the mists of time, but I'll check my files and see. A thought is that since NAA is often considered to be an analog for Indole Acetic Acid (thus, sort of biopesticidelike), perhaps that prompted EFED to require only a little ecotox. data. Also, considering how long NAA has been around, perhaps ecotox, requirements started very low, and its biopesticidelike activity kept them low. Just guessing, though.

Rick Keigwin (our Branch Chief) requests that he, my PM (Dennis McNeilly), and I all be invited to the NAA SMART meeting on April 9.

John Bazuin

<<<<0>>>>

Tyler Lane



Tyler Lane

To: John Bazuin/DC/USEPA/US@EPA

CC:

03/26/03 04:26 PM

Subject: NAA Walver Info

.John-

I've been going over the guideline data requirements and am curious about the dearth of eco toxicity and fate data that seems to have been required. In your files, do you have any record of why so little data was called in and the letters accepting the waiver requests? I'm out of the office until Monday, but if you have anything, I can stop by then- Tyler

Chemical Review Manager Office of Pesticide Programs

Special Review and Reregistration Division

MC: 7508C

U



John Bazuin

03/31/03 11:13 AM

To: Tylor Lano/DC/USEPA/US

cc: John Bazuin/DC/USEPA/US@EPA

Subject: Re: NAA Waiver Info

Tyler,

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John Bazuin

<<<<0>>>>





Tvier Lane

To: John Bazuin/DC/USEPA/US@EPA

co:

03/31/03 08:19 AM

Subject: Re: NAA Weiver Info[8]

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Chemical Review Manager Office of Pasticide Programs Special Review and Reregistration Division

MC: 7508C

Phone #: (703) 305-2737 Fax #: (703) 308-8005

John Bazuin



John Bazuin

To: Tyler Lane/DC/USEPA/US@EPA

cc:

Subject: Re: NAA Waiver Info

Tylor,

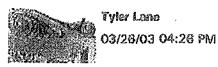
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John Bazuin

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Tyler Lane



Tyler Lano

To: John Bazuin/DC/USEPA/US@EPA

cc:

Subject: NAA Waiver Info

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Chemical Review Menager Office of Pesticide Programs Special Review and Reregistration Division

MC: 7508C



Tyler Lane

MA 81:80 EO\15\80

To: John Bazuin/DC/USEPA/US@EPA

ce:

Subject: Re: MAA Weiver Info

john-

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Chemical Review Manager
Office of Pesticide Programs
Special Review and Reregistration Division

MC: 7508C

Phone #: (703) 305-2737 Fax #: (703) 308-8005

John Bazuin



John Bazuin

To: Tyler Lane/DC/USEPA/US@EPA

03/26/03 04:44 PM

Subject: Re: NAA Waiver Info@

cc:

Tyler,

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John Bazuin

くくくくロンシン>

Tyler Lane



Tyler Lane

03/26/03 04:26 PM

To: John Bazuin/DC/USEPA/US@EPA

CC;

Subject: NAA Weiver Info

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Chamical Review Manager Office of Pesticide Programs Special Review and Reregistration Division MC: 7509C



John Bazuin 03/28/03 04:38 PM

To: Tylar Lane/DC/USEPA/US

CC:

cc: John Bazuin/DC/USEPA/US@EPA

Subject: Re: NAA Woiver Info

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John Bazuin

<<<<0>>>>>

Tyler Lane



Tylor Lone

To: John Bazuin/DC/USEPA/US@EPA

66;

09/26/03 04:26 PM

Subject: NAA Weiver Info

John-

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Chemical Review Menager Office of Pesticide Programs Special Review and Reregistration Division

MC: 7508C



To: Dennis McNeilly/DC/USEPA/US@EPA, John Bazuin/DC/USEPA/US@EPA

cc:

Subject: MAA Smart Meeting

Please touch base with Tawanda to make sure that we are invited to this SMART meeting.

<u>NAA SMART Meeting Set for April 9</u>. The SMART Meeting for naphthaleneacetic acid and its derivatives has been set for the morning of April 9. The meeting will take place between the technical registrant Amvac and OPP's reregistration team, here in Crystal Mall II. (Tyler Lane, 305-2737)

119

6



Rafael Prieto 03/14/03 03:41 PM To: Tyler Lane/DC/USEPA/US@EPA, John
Bazuin/DC/USEPA/US@EPA, Allen
Vaughan/DC/USEPA/US@EPA, Ray Kent/DC/USEPA/US@EPA,
Nicole Mosz/DC/USEPA/US@EPA, Roger

Clark/DC/USEPA/US@EPA
cc: Sid Abel/DC/USEPA/US@EPA, Tom Bailey/DC/USEPA/US@EPA,
Betsy Behl/DC/USEPA/US@EPA, Donna
Davis/DC/USEPA/US@EPA, Marion
Johnson/DC/USEPA/US@EPA, Arnet

Jones/OC/USEPA/US@EPA, Richard

Keigwin/DC/USEPA/US@EPA, Ray Kent/DC/USEPA/US@EPA, Susan Lawrence/DC/USEPA/US@EPA, Meredith

Laws/DC/USEPA/US@EPA, Amold Layne/DC/USEPA/US@EPA,

Susan Lewis/DC/USEPA/US@EPA, Daborah McCall/DC/USEPA/US@EPA, Michael Mcdavit/DC/USEPA/US@EPA, Robert Mcnally/DC/USEPA/US@EPA, Michael

Metzger/DC/USEPA/US@EPA, Kathy Monk/DC/USEPA/US@EPA,

Margaret Rice/DC/USEPA/US@EPA, Doug Sellers/DC/USEPA/US@EPA, Betty Shackleford/DC/USEPA/US@EPA, Mah

Shamim/DC/USEPA/US@EPA, Dana Spatz/DC/USEPA/US@EPA,

Thomas Steeger/DC/USEPA/US@EPA, Donald

Stubbs/DC/USEPA/US@EPA, Pauline Wagner/DC/USEPA/US@EPA, David

Widawsky/DC/USEPA/US@EPA, OPP BEAD Reregistration Team,

Michael Goodis/DC/USEPA/US@EPA, Anne Overstreet/DC/USEPA/US@EPA, Cynthia Gilds-Parker/DC/USEPA/US@EPA

Subject: NAA (CASE 0379) BEAD RED Package

Click on each of the four (4) tabs to access the information inside.

| | CASE NAME (CASE NUMBER | R) |
|-----------------|--|-----------|
| Chemical Number | Chemical Name | Status |
| 56001 | I-Naphthaleneacetamide (NAD) | Completed |
| 56002 | 1-Naphthaleneacetic acid (NAA) | Completed |
| 56003 | 1-Naphthaleneacotic acid, potassium salt | Completed |
| 56004 | 1-Naphthaleneacetic acid, ammonium soft | Completed |
| 56007 | 1-Naphthaleneacetic acid, sodium salt | Completed |
|)56008 | l-Naphthaleneacetic acid, ethyl ester | Completed |

Document Links to the following Label Data reports of Chem () are attached. Click once on the Document Links

to view the database record. To print each report, LAUNCH the attachment in WordPerfect or Lotus 1-2-3, as appropriate. You can also DETACH the files and then print from the appropriate program. NOTE: You should not attempt to print directly from Lotus Notes, since the attachments will not print correctly.

LABEL DATA (LUIS) REPORTS

| Divisio | Link | Report Name | Division | Link | Report Name |
|------------------|------|---------------------------------------|------------|----------|--------------------------------|
| n SRRD RED | | Appendix A Spreadsheet Use Profile | HED HED | Aftern . | Table A2 Now! Table A3 Now! |

| | red | Usage Data (% crop treated, etc)*** Label Issues Label Tracking (changes since last update) | MED EFED EFED/MED | | HED Label Data Spreadsheet Env. Fate & Effects Spreadsheet Full General Chemical Report |
|---|-----|---|-------------------------|--------|---|
| ſ | | . 5 into the line of ABA Bours | almammeimm em | WA KEN | W733 rEAn |

Link to list of OPP Reregistration team **E42** [2].

information

(like percent crop treated) and a meeting will be setup to address your specific usage needs.

Vocabularies Used on Spreadsheet Reports

| Code | Link | <u>Vocabulary Type</u> |
|--------|------|--|
| G C | | Geographic Vocabulary Crop/Site Limitations |
| H | | Pre-harvest Limitations |
| 5 | B | Pre-slaughter Limitations |
| F | | Feeding and Grazing Limitations |

INSTRUCTIONS - To complete this form

- Choose 'Reply with History' from the Icon bar,
- Delete the choice that you don't want when answering a Yes/No question,
- Move your cursor to the line below the question to type in a response,
- Click the 'Send' button from the icon bar when finished.
- 1. What is your Division?

Please type your answer here:

2. What is your Branch?

Please type your answer here:

3. Did you receive the reports in a timely manner?

Yes No

4. Were the data reports helpful in your preliminary review of this chemical (and its associated registrations)?

Yes No

4a. If your answer is No, how could the reports be improved to better help you in your review of this chemical?

Mease type your answer here:

5. Were the reports legible?

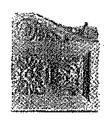
Yes No.

5a. If your answer is No, please explain.

Please type your answer here:

6. Do you have any additional comments or questions? Please type your answer here:

Satisfied with your responses? If so, please click the 'Send' button from the icon bar to submit this form. Thank you.



T**yle:** Leno 03/11/03 03:43 PM

To: Meh Shamim/DC/USEPA/US@EPA, Allen
Voughen/DC/USEPA/US@EPA, Ray Kent/DC/USEPA/US@EPA,
Michael Goodis/DC/USEPA/US@EPA, John
Bazuin/DC/USEPA/US@EPA, Michael Goodis/DC/USEPA/US@EPA,
Neil Anderson/DC/USEPA/US@EPA, Steve
Jarbos/DC/USEPA/US@EPA, Nicole Mosz/DC/USEPA/US@EPA,
Roger Clark/DC/USEPA/US@EPA

CC:

Subject: NAA SMART Meeting

All-

The technical registrant, Amvac has responded to the SMART letter for naptheleneacetic acid (NAA) with proposed dates of either April 8 or 9. I am hoping to have a full reregistration team assembled in the next week and respond with a firm date for the meeting. Please let me know if either of these dates conflict with any significant upcoming OPP events.

Thanks, Tyler

Chemical Review Manager
Office of Pesticide Programs
Special Review and Reregistration Division
MC: 7508C



Tylor Leno

03/06/03 01:43 PM

To: John Bazuin/DC/USEPA/US@EPA

cc:

Subject: NAA Reg Standard

John-

I have located a copy of the napthaleneacetic acid registration standard issued august 1981. I was only able to find a single copy in the end file room, but let me know if you need it to develop a case history-tyler

Chemical Review Manager Office of Pesticide Programs Special Review and Reregistration Division

MC: 7508C



John Bazuin 03/08/03 08:43 AM

To: Tyler Lane/DC/USEPA/US

60:

cc: John Bazuin/DC/USEPA/US@EPA Subject: Re: NAA: registration standard

Tylor,

I looked through all of my NAA & Salts stuff but did not find the Registration Standard. That must mean that I never encountered it in the product jackets (but I haven't looked through every one) and didn't inherit a copy from anyone else. If you find it, I'd be interested in getting a copy. I'll keep thinking about it, to see if I can figure out a place to get one.

John Bazuin

<<<0>>>>

Tyler Lane



Tyler Lene To: John Bezuin/DC/USEPA/US@EPA

03/05/03 08:00 PM (

Subject: NAA: registration standard

Were you able to locate a copy of the Reg Standard for NAA? I did not see one in my files but I am looking in some other storage areas- Tyler

Chemical Review Manager
Office of Pesticide Programs
Special Review and Reregistration Division

MC: 7508C

Meeting Agenda 10:00-11:00 am March 5, 2003

Ron. 504

Napthaleneacetic Acid (NAA) 056001, 056002, 056003, 056004, 056007, 056008

Aftendees:

SRRD Michael Goodis

EFED Mah Shamim

Tyler Lane

Allen Vaughan

HED Ray Kent **BEAD Rafael Prieto**

Dave Widawsky

RD John Bazuin

Topics:

BEAD

Quantitative Usage Analysis

Label Packages

Potential for Use Chapter- application methods, where used, rates, timing

Data needs for SMART Meeting

HED

Data needs for SMART Meeting

Timelines for committee meetings

Metabolite information

EFED

Data needs for SMART Meeting

Dates for deliverables

Metabolite information

Potential for endangered species concerns

SRRD

SMART meeting date

Use Closure Memo

Pre SMART meeting information from registrant

RD

Any new or conditional uses
Recisional conditional con Registered use information - Toy to do by end of April

Identify alternatives of reduced risk chemicals --- classes from

Principal registrant is Amuse Smart meeting in April



Tyler Lane 03/04/03 09:34 AM

To: Allen Vaughan/DC/USEPA/US@EPA, Mah
Shamim/DC/USEPA/US@EPA, Ray Kent/DC/USEPA/US@EPA,
Michael Goodls/DC/USEPA/US@EPA, Anne
Overstreet/DC/USEPA/US@EPA, John
Bazuin/DC/USEPA/US@EPA, Steve Jarboe/DC/USEPA/US@EPA,
Rafael Prieto/DC/USEPA/US@EPA

CC:

Subject: NAA Scheduling Meeting

All-

I have attached a tentative agenda for tomorrow's meeting. If you would like to discuss any additional items, please contact me and I will insert them into the agenda.



Team Meeting 3-5-03.

Chemical Review Manager
Office of Pesticide Programs
Special Review and Reregistration Division

MC: 7508C



Tyler Lane

03/05/03 06:00 PM

To: John Bazuin/OC/USEPA/US@EPA

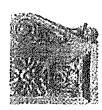
cct

Subject: NAA: registration standard

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Chemical Review Manager
Office of Pesticide Programs
Special Review and Reregistration Division

MC: 7508C



Tuior Lane 09/05/09 10:51 AM

To: Allen Vaughan/DC/USEPA/US@EPA, Nicole Mosz/DC/USEPA/US@EPA, Rafael Prieto/DC/USEPA/US@EPA. Steve Jarboe/DC/USEPA/US@EPA, Ray Kont/DC/USEPA/US@EPA, John @ozalin/DC/USEPA/US@EPA

ĉС:

Subject: NAA SMART Meeting Letter to Registrant

All-

I've attached the SMART request letter to the registrant for your review. If you have any additional questions or comments, let me know as soon as possible, as we are hoping to notify the registrant of the Agency's timeline in the next week. Additional questions may also be added to the follow-up letter setting the firm date for the SMART meeting, to be issued in approximately two weeks. I've also attached a fact sheet I have created for this chemical for reference purposes. If any of you have additional questions or data needs, please to contact me.





SMART Letter 2-26-03. Naphthaleneacetic Acid Facts.

Thanks. Tyler

Chemical Review Manager Office of Pesticide Programs Special Review and Reregistration Division

MC: 7508C

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460



OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Certified Mail

Mr. Jon Wood Amvac Chemical Corp. 4695 MacArthur Ct., Suite 1250 Newport Beach, CA 92660-1706

Dear Mr. Wood:

As part of the pesticide reregistration eligibility process, the Agency is requesting the participation of Amvac Chemical Corporation in a "SMART" meeting for the plant growth regulator, napthaleneacetic acid (NAA) and its derivatives. The main purpose of this meeting is to review the available use related information for NAA formulations that are marketed by Amvac. The Agency plans to arrange this meeting for the end of March/early April of this year; the meeting should last approximately two hours. In the past, the EPA has considered the information provided by registrants in SMART meetings to be extremely helpful. Information you provide will be used, as appropriate, to refine the exposure and risk assessments which are an integral part of the Reregistration Eligibility Decision (RED) document for this compound. The use related information that you present could also permit the EPA to conduct more realistic risk assessments and to decrease the Agency's reliance on default assumptions.

In the past, the Agency confirmed its use information with the registrant at various times during the RED development process. If clarifications were made, then it was often necessary to conduct time-consuming modifications to the exposure and risk assessments. The statutory deadlines of the Food Quality Protection Act (FQPA) require the Agency to eliminate such process inefficiencies. To meet FQPA deadlines, the Agency must have comprehensive information about the use and usage of NAA at the initiation of the risk assessment process. The SMART meeting also allows the Agency and registrant the opportunity to discuss any ongoing studies, potential label modifications or changes in use patterns that may impact the reregistration process.

In preparation for the SMART meeting, the NAA RED team has identified the following issues for discussion:

(1) How much NAA is used annually in the US? How much is sold annually in the

- US? What is the geographic/regional distribution of usage? Is there information available on the use of NAA for each registered use site, in particular, the number and percentage of acres treated annually and total number of pounds applied per year or crop cycle?
- (2) What is the market miche for NAA? What are the key pests or other conditions that drive the use of NAA? Please discuss on both a regional and national basis.
- (3) Which agricultural uses will be supported by Amvac? Are there any crops that Amvac does not intend to support as a US registration, but will support as a tolerance for imported commodities? Are there any nonagricultural uses?
- (4) Will supported uses be at the maximum label rates, number of applications, and the application intervals as currently stated on the label? Are there any anticipated planned label changes? If so, what are these planned changes? If there are any uses that you are not supporting for reregistration, are you aware of anyone who will be supporting these uses?
- (5) Please describe all methods of application (air, ground, hand, chemigation, soil injection, etc.).
- (6) Please describe all registered formulations for occupational and residential use. Is NAA used in combination with any other pesticide?
- (7) Please describe any uses that may potentially be used in residential, recreational, or other public (non-occupational) settings.
- (8) What are the maximum and average application rates? Do these use rates differ from the maximum rates allowed on the label? For food uses, what rates are supported by the submitted residue chemistry data?
- (9) How many applications (maximum and average) are made per season? How many applications are made per crop or per year? What is the timing (months) of applications and re-treatment intervals (minimum, maximum and typical)? Are there regional differences to these application patterns?
- (10) How many acres are generally treated by an applicator per day and per season?
- (11) Describe the types of worker activities impacted by re-entry intervals (REI) for NAA, including any restrictions (such as number of acres that can be treated by an individual). What is the typical length of pre-harvest intervals (PHIs) for different crops?

- (12) Is NAA used as a post-harvest treatment to the harvested commodity or parent plant? Are concentration factors associated with post-harvest processing (washing, trimming, blanching), transport, storage, or cooking?
- (13) Please describe equipment used for mixing, loading, and application especially for uncommon uses.
- (14) Will Amvac be supporting any special local needs (SLN) registrations?
- (15) Are there any feeding/grazing restrictions on NAA product labels?
- (16) Are there any other existing restrictions, such as for groundwater? Please describe specific uses and areas/sites to which the restriction applies.
- (17) Are you aware of any metabolites or degradates of NAA?
- (18) What alternatives to NAA are available? We are particularly interested in alternatives for the crops with the highest NAA use. Are there any constraints to their use, such as cost or efficacy? Is there any geographic area where there are no alternatives? What is unique about NAA?
- (19) Are there any new toxicology or chemical-specific exposure monitoring data or biomonitoring data available?

We understand that you may not be able to fully address all of the above questions; however, all of the above information could be useful when we conduct the exposure assessments for NAA. Additional information may be requested at a later date.

It would also be very useful if your company would develop a short, concise handout which reflects the information to be presented at the meeting. Also, to ensure that a complete record of the meeting is available, please provide any use related information that you present in written form. If the information that you present contains large tables, an electronic format can speed the Agency's review process. If any of the information you present to the Agency is Confidential Business Information (CBI), please identify it as CBI to ensure that it is treated as such.

OPP believes that a Use Closure memo may be necessary for NAA. This memo would serve as a memorandum of understanding between OPP and Amvac regarding uses supported for reregistration, as well as the maximum label rates per acre or crop cycle, number of applications, and the application intervals. The availability of such a document that has been mutually agreed upon could minimize unnecessary rework as the Agency finalizes the risk

assessment documents.

Please note that SMART meetings are not a forum for diagnosing how the Agency conducts risk assessments, discussing how cumulative risk assessments are going to be accomplished, or negotiating Reregistration decisions. Registrants and others will have opportunities elsewhere in the RED development process to engage in these discussions.

Enclosed is a list of the team members for the NAA RED and their corresponding science disciplines. I will be calling you shortly to arrange the meeting date and time. Please provide me with a copy of an agenda for this meeting as well as a list of who will be representing Amvac so that I may distribute it to the team members. I can be reached at (703) 305-2737 if you should have any questions or comments concerning this meeting.

Sincerely,

Tyler Lane, Chemical Review Manager Reregistration Branch III Special Review and Reregistration Division (7508C)

Attachment: NAA RED Team Members

Attachment

NAA Team Members:

HED:

Ray Kent

EFED:

Mah Shamim

Allen Vaugben

BEAD:

Rafael Prieto

Steve Jarboe

RD:

Jim Bazuin

SRRD:

Tyler Lane

March 6, 2003

Naphthaleneacetic Acid: 1-Naphthaleneacetic acid

PC Code: 056001, 056002, 056003, 056004, 056007, 056008 Case #: 0379 CAS: 86-87-3 CFR: 180.155

Registrant Contact: Amvac Chemical Corp.

Jon Wood (Darryl Brock) 4695 MacArthur Ct., Suite 1250 Newport Beach, CA 92660-1706

(949) 260-1212

jonw@amvac-chemical.com

United Agri Products (Platte Chemical)

Scott Baker 419 18th St. Greely, CO 80631

(970) 347-1468 fan (970) 347-1565

scott.baker@uan.com

Team: RD John Bazuin (rm 255)

HED Ray Kent (BC) EFED Mah Shamim (BC)

SRRD Tyler Lane 305-2737

BEAD

Steve Jarboe, Nicole Mosz

USDA

PRB

Type: Plant Regulator

of Products: 4 056001:

> · Manufacturing Use Products: 1 Technical 5481-431 (Amvac)

 Pesis: plant growth regulator Uses: fruit, flower, ornamental

056002: # of Products: 15

Manufacturing Use Products: 4

Technical 5481-219, 430, 498 (Amvac Chemical Co.) 34704-628 (Platte Chemical Co., Inc.)

· Pests: anthracuose, plant growth regulator

· Uses: gooseberry, apple, pear, ornamental, flower

· # of Products: 12 056003:

(potassium salt)- Manufacturing Use Products: 0

· Uses: aerial, citrus, apple, pear, olive, holly

056004: # of Products: 7

(ammonium salt) Manufacturing Use Products: 0

Uses: serial, cutting dip (citrus, apple, pear, olive, cherry)

056007: # of Products: 7

(sodium salt) • Manufacturing Use Products: 3

Technical 5481-218, 432 (Amvac Chemical Co.) 34704-629 (Platte Chemical Co., Inc.) · Uses: sprays (apple, pear, olive, serial, catalpa, elm, maple, horsechestnut)

056008:

• # of Products: 8

(ethyl ester)

· Manufacturing Use Products: 1

Technical 5481-433

· Uses: citrus, apple, pear, olive, pomegranate, ornamental, tree

Tolerances: 11

| Commodity | PPM | |
|--|---------------------------------------|------|
| المستحدد المستحدد المستحدد المستحدد المستحدد المستحدد المستحد المستحدد المس | | |
| Apple | ì | |
| Cherry, sweet. | 0.1 | |
| Olive | 0.1(N) | |
| Oranges | 0.1 | |
| Pear | 1 | |
| Pineapple (from the a | application of the sodium salt to the | 0.05 |
| Quince | 9 | |
| Tangerine | 0.1 | |
| | | |

(b) Tolerances are established for residues of the ethyl ester of 1-naphthaleneacetic acid in or on the following raw agricultural commodities:

| Commodity | PPM |
|-----------|--|
| ~++ | ************************************** |
| Apple | Î |
| Pers | Ī |
| Olive | 0.1 |

Issues:

| | Steps Taken | Contact | Phone Number | Date | Re- Date | Resolution |
|--|---|---------|-----------------|------|-------------|------------|
| | *************************************** | | | | 777.00 | |

mellow Coft The face

State Highway 690 P.O. Box 25 Greenwood, 7A 22943

Attention: B. Shannon Roberts

Gentlemen:

Subject: RPA Registration No. 11546-1 EPA Registration No. 11546-2

Your Submission of March 20, 1984 - Revised

Confidential Statements of Formula

Product Chamistry raview of your above submission indicates that you have adequately adjusted your Confidential Statements of Foreula to correct deficiencies identified by their previous review.

Sincerely yours,

Robert J. Raylor Product Manager (25) Funcicide-Herbicide Franch Pegistration Division (TS-767C)

RD/FHB: JDE: 69802: Taylor: RD-55:eq: Kenderick: 898-1270: 12/5/84: Del/12/12/84

From 4/4/84 TSS/CH 12/19W

minimise. It is all the all the states of a solution of a state. And a solutions in the state of a solution of a s

P. O. BOA Lant @ 1.74 A HARRIS 51 @ CHARLOTTES HIL. VA. 22903 PHONE GOLD TOTALL

GREENWOOD CHEMICAL COMPANY Greenwood, Virginia

E: :: ASSAY

Test Conditions: On July 15 and 16, 1976, a twenty-four hour static bioassay was conducted using blue gill sunfish finnerlings (Legonis macrochirs
in wastewater from the final lagoon at the Greenwood Chemical Company.
The wastewater was used at full-strength and at various dilutions, made on
a logarithmic scale with water from a nearby farm pond. The test was conducted in an air conditioned building at Greenwood Chemical Company using
replicate 53 Liter (14 gallon) samples in plastic containers. The water
was constantly aerated, keeping dissolved oxygen levels above 5 mg/l. The
fish weighed 3 to 5 grams each, and five individuals were stocked per container, a rate of 2.7 to 3.5 Liters/gram of fish. The fish were supplied
by The Perry Ninnow Farm, Windsor, Virginia.

No fish mortality due to the toxicity of the water was recorded either with the full-strength wastewater or with the diluted water; however, one fish jumped out and expired. The fish displayed no obvious irritability of erratic behavior, especially when first introduced into the containers.

Table of Dinassav Mesults

| | Dilu | tion | | | |
|-------------|--------------|--------------|-----------|---------------------|-------------------|
| Container # | % Wastewater | y pond Water | <u>na</u> | Initial No. of Fish | Final No. of Fish |
| 1 | 100 | 0 | 9.5 | 5 | 4 4 |
| 2 | 100 | 0 | 9.4 | 5 | 5 |
| 3 | 87 | 13 | 9.3 | 5 | • 5 |
| 4 | 87 | . 13 | 9.3 | 5 | 5 |
| 5 | 75 | 25 | 8.8 | 5 | 5 |
| 6 . | 75 * | 25 | 0.8 | 5 | 5 |
| 7 | 65 | 35 | 8.5 | 5 | |
| 8 | 65 | 35 | 8.6 | 5 | ₩ <u>6</u> |
| 9 | 0 | 100 | 7.9 | \$ | 5 |
| | | | | | |

One fish jumped out.

Based on this twenty-four hour static bloassay, the water tested from the final lagoon at Greenwood Chemical Company was found to be non-toxic.

production of the control of the production of the control of the

P. 10 Phil Shall @ 1.29 A HARRIS ST @ CHARLIST TEST HER. VA. 22903 PHONE (801) 295-4710

GREENWOOD CHEMICAL COMPANY Greenwood, Virginia

E! (ASSAY

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Table of Rioassav Results

| | Dilu | tion | | | |
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| Container # | % Wastowater | y Pond Water | <u>pii</u> | Initial No. <u>of Pish</u> | Pinal No. of Fish |
| 1 | 100 | 0 | 9.5 | \$ | 4 2 |
| 2 | 100 | 0 | 9.4 | S | 5 |
| 3 | 87 | 13 | 9.3 | 5 | • 5 |
| 4 | 97 | . 13 | 9.3 | 5 | 5 |
| 5 | 75 | 25 | 8.8 | 5 | 5 |
| 6 | 75 - | 25 | 8.8 | \$ | 5 |
| 7 | 65 | 35 | 8.5 | 5 | , S |
| 8 | 65 | 35 | 8.6 | 5 | 5 |
| 9 | 0 | 100 | 7.9 | 5 | 5 |

*One fish jumped out.

Based on this twenty-four hour static bioassay, the water twated from the final lagoon at Greenwood Chemical Company was found to be non-toxic.

- 1 6 1983

Greenwood Chemical Co. State Highway 690 P.O. Box 25 Greenwood, VA 22943

Attention: B. Thennon Roberts

主机组织的美俚的杂词

Subject: 1-Maphthalana Acolic Acid Softon Salt EPA Recistration No. 11546-1 1-Waphthalana Acotic Acid SEA Registration No. 11546-26 Your Letter of July 11, 1983

For EPA Registration Mos. 18545-3 and 18545-2, you must verify the May 23, 1983 Formulation statement. Reserve on our relcolations, the rotal weight of the batch is sent and sent repactively, not the sent and sent indicated on the Confidential Statements of Formula.

por CPA Registration No. 11546-1, the formulation as it presently stands will not support a 98.0% active incredient claim. Please review the formulation and submit a revised Confidential Statement of Formula.

for FFA Registration No. 11045-2, the tabel states 05.5% active ingredient which is not supported by your Confidential Statement of Formula. Please provide us with a revised Confidential Statement of Formula that will support your product's label claims. Inose label claims must be supported by an assay or pinjous progent purity of the active ingredient supported by analytical data.

under the Precautionary Statements and the statements "Warmful if inhaled. If inhaled, remove victim to Fresh air. If not breathing, give attificial respiration, preferably nouth-to-mosth. Get padical attention."

The precontionary statements must include the following: "Marning. Causes substantial but temporary eye injery. "Assmind if evallowed or absorbed through skin. Avoid contact with skin, eyes or clothing. If in eyes, wash with planty of water. Car medical attention immediately. If reallowed, drink a large quantity of vater and induce vomiting by placing linger in back of throat. Get medical attention. Hever give anything by routh to an unconscious person. If on skis, wash thoroughly with scap and water. Get medical attention if irritation persons."

Defer to proloced popy for appropriate Storage and Disposel Statements

Place abbait five explor of finished laboling incorporating the charachanges. Also, correct Confidential Statements of Portuin on requested above.

Dinceraly yours,

Robert J. Snyler Product Hausger (25) Punglaide-Serbiotão Bromeh Registration Dividing (75-7676)

Drivevell, James BCB-31942; Walte-02514: DyG: Davon: 078-2013:9/7//63

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| 1-Naphthaleneauti Ac | 12 98.5 % |
| ACTIVE INGREDIENT | (S) ; |
| FILE(S) REFERENCED: | |
| SUBMISSION PURPOSE: | |
| TO: TEAM 21 () 23 () 25 (U | • |
| FROM: FHB/TSS T. Aiken E 0/4/83 | • |
| SUBJECT: EPA FILE SYMBOL //546-2 | APPLICANT: Green was of |
| REC'D BY CHEM. | NO. (·) |
| | REVIEW COMPLETED: 9/4/83 |
| REC'D BY DIV. | |
| DATE: SUBMITTED: REC'D BY DIV. | review started: 8/4/83 |

State Highway 690
P. O. Box 26
Greenwood, Virginia 22943

Telephone 703 456-6832

July 13, 1983

Robert J. Taylor Product Hanager 25 Rogistration Division (78767-0) ENVIRONMENTAL PROTECTION ACRECY 401 L. S. met, S.K. Washington, D.C. 20460

Dear Mr. Taylor:

On April 5, 1983, I broke to you, copies enclosed, staling that we chose to use the combination of alternate and cite-all method of tata support. On thus same date, I indicated that we were in discussion with Union Carbice on compensation on using their mata. We did not receive an answer from you. On April 11, 1983 in my lelter to you I stated that we are now preparing to notify Union tarbide and request another meeting. In this letter, copy attached, we had a week lown of what drien Carbide wanted to charge us, what they had actually paid, and the price range from Bioassay Corroration whereby we could get the data for purselves. In June 20, 1983, I wrote to Er. Davis am. asked him to give us the bottom dollar that Union Carbide would consider for using their tata. I saw no reason why we should pay replacement cost of over \$500,000 when the actually post of those sest was a little over \$266,000, and our cost for having the work done ourselves would be a little over \$227,000. To seems than union tartile is taying to make money by selling these was. On July 15, 1983, I received a letter from Union Carbide where they say that they wanted one half of Joly, 900 for a m share of the registration. We have notified Diseasely to commence performing these jest foris. In Union Carbine's letter yair Sply S, 1983, they stated that if so die not pay this came (\$ of \$619.000) that they were going to demand binding arbitration. As I stated before, on have colified Bloassay to commence making the tout for us.

We have reported to you that Union Carbine continuous to tell our castomers, that they are the only one that has an often tabel. We have notified our customers, by letter than this sectemen, is no true, and have been assured by your geople....

we have been movified by mr. Assumen of only two things that were redected to complete our re-registration. We have submitted these with return receipt, and have not been about them as this line.

State Highway 690 P. O. Box 26 Greenwood, Virginia 22943

Telephone 703 456-6832

Robert J. Caylor Page 2 July 18, 1983

There are a number of different questions that we have asked concerning Union Carbide's illegal importation of 1-Haphthalene Acc ic Acić in 1980-31. Those product did they use to conduct these test? What about the legallity of issuing labels with two parity costerns?

We are proceeding with Biusesay Corporation to do our west work, and will await Union Carbide's threat of arbitration and JPA's approval of our re-registration.

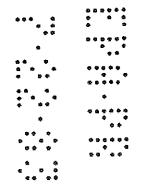
Convially yours,

Ginton G. Whipman

President

003/bar

Enclosures: 1



April 5, 1983

Robert J. Taylor Product Manager 25 Registration Division (TS767-0) ENVIRONMENTAL PROTECTION AJENCY 401 h. Street, S.Y. Washington, D.C. 20460

Dear Mr. laylor:

I uncerstant that the cite-all method of data support is no longer required in order to secure reregistration under my pending application for 1-Naphthalens Acetic Acid, identified as registration number 115%6-2 and submitted on November 6, 1981. I hereby choose the alternate or combined alternate and cite-all method of data support. I have already submitted all the required data compensation forms for that method of support.

We are in discussion with Union Larbide on compensation, if we choose to go that route. We are waiting on development from $\mathcal{P}A$ and their new approach to the implementation of FIFRA sec. 3(c)(1)(0).

Cordially yours,

Clinton C. Shipman President

CCS/ber

April 5, 1983

Robert J. Paylor
Product manager 25
Registration Division (TS-767-C)
ENVIRONMENTAL PROTECTION AGENCY
401 M Street, 9.W.
Washington, D.C. 20460

Dear Fr. 14ylors

I understand that the cite-all method of data support is no longer required in order to secure reregistration under my pending application for 1-Naphthalene Acetic Acid Sodium Salt, identified as registration number 11546-1 and submitted on November 6, 1981. I hereby choose the alternate or combined alternate and cite-all method of data support. I have already submitted all the required data compensation forms for that method of support.

de are in discussion with Union Carbide on compensation, if we choose to go that route, do are waiting on development from SFA and their new approach to the implementation of FIFRA sec. 3(c)(1)(D).

Cordially yours,

Clinton C. Snipman Procident

CCS/bar

The Greenwood Chemical Company

State Highway 690
P. O. Box 26
Greenwood, Virginia 221

Yelophone 703 456-683:

April 11, 1983

Robert J. Taylor

Product Manager 25

Registration Division (TS-767-C)

ENVIRONMENTAL PROTECTION AGENCY

401 K Street, S.W.

Washington, D.C. 20460

Dear hr. Taylor:

Ref: NAA Registration

1-Naphthalene Acetic Acid Sodium Salt

EPA Registration No. 11546-1 1-Naphthalene Acetic Acid EPA Registration No. 11546-2

On March 11, 1983 I wrote you concerning registration of 1-Naphthalene Acetic Acid. We have now obtained information from Bioassay Corporation concerning the test that needs to be performed. Enclosed is a comparison of the price range submitted by Bioassay, Union Carbide's actual cost, and Union Carbide's estimated replacement cost.

We are now prepared to notify Union Carbide and request another seeting. Before we make contact, we would appreciate you informing us just how the PR NOTICE 83-1 affects our situation with Union Carbide, and how we should proceed with the situation.

Cordially yours,

Clinton C. Shipman

President

CCS/bsr

Enclosure

cc: Kevin Braumberg, SBA Marc Jones, EPA

Warrer Davis, Union Carbide

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b Dose Feed Administration c 14 Day Range Finder

e <u>In Vitro</u> Cytogenetics f <u>Sister Chromatid</u> Exchange

d Chinese Hamster Ovary Cytotoxicity Test

State Mighway 690 P. O. Box 26 Greenwood, Virginia 22942

Telephono 703 466-6832

| • | TEST | union carbide est. Repl. Cost | union carbide actual cost | PRICE RANGE SUBMITTED BY BIOASSAY CORP. |
|---|--|----------------------------------|------------------------------|---|
| | 163.82-1 Subohronic Oral Toxicity | Rats 100,000 Dogs 200,000 | 29,110 67,000 | 62,000 - 75,000 55,000 - 65,000 9,000 - 11,000 |
| | 163.83-3 Teratology | Rat 35,000 Rabbit 50,000 | 7,400 50,000# | 23,000 - 26,000 29,000 - 33,000 |
| | Residue | ? 4, 999 | 72,368 | |
| | 163.84-2 163.84-3 163.84-4 Mutagenicity | 19,700 | 16,425 | Amen test 850 gach 5,000 - 8,200 ° 3,500 - 4,500 ° 3,500 |
| | 163.161-1 Hydrolysis or Dissociation | 22,000 | 21,847 | 989868 9 9 9 9 0 6 96 90999 9 9 |
| | * Estimated Cost - S | tudy in Progress | | |
| | ** Pending | | | ര്ര്മ ശേരദേശ ദേര മ ദേര ദേര ദേര ദേര |
| | a Gavage Administrati | lon | * | 44 94 |

June 20, 1983

Warren A. Davis
Registration Manager
Herbicides/Growth Regulators
UNION CARBIDE ACRICULTURAL PRODUCTS COMPANY, INC.
T.W. Alexander Lrive
P.O. Box 12014
Research Triangle Park, N.C. 27709

Door Mr. Davie:

We have not had a firm answer from EPA concerning use of data in our registration. There is no need for us to wait until we hear from them. If you would give us the bottom dellar that you would take for use of your data for the test listed below, then we will consider negotiating with you. Otherwise, we will nove to obtain our own data.

Ret Teratology study with preliminary range finder

Rabbit Teratology study with prolimenary range finder

Rosidue Data

Dissociation Data

Fish Acuto LC₅₀

Asute Texicity to Aquatic Invertebrates

Subohrowio Oral Toxicity

Mutigerielty Assays

Condially yours,

Clinton C. Sulpuna Procident

ccs/ba

600000



UNION CARBIDE AGRICULTURAL PRODUCTS COMPANY, Inc.

P. O. BOX 12014, T. W. ALEXANDER DRIVE RESEARCH TRIANGLE PARK, N. C. 27709

/9191549-2000

CERTIFIED MAIL NO. P 379 934 102 RETURN RECEIPT REQUESTED

July 8, 1983

Mr. Clinton C. Shipman, President Greenwood Chemical Company P. O. Box 26 Greenwood, VA 22943

Dear Mr. Shipman:

We have received your correspondence of June 20, 1983, listing certain data relating to Naphthaleneacetic acid (NAA), Technical Sodium Saltiof NAA. and Technical Naphthalene acetamide which you are interested in citing to the U.S. Environmental Protection Agency for registration purposes and for which you have offered to pay Union Carbide compensation. As reconfirmed to you in our July 1, 1983, conversation, the value of our data and costs to maintain registration is still \$619,634 as initially identified in our November 30, 1982, correspondence. Your share, as the only other registrant, would be one-half that sum or \$309,817.

We have negotiated in good faith in an attempt to derive fair compensation for our existing data base and to reach an agreement on cost sharing for additional new data that must be developed in order to maintain registrations under the EPA Standards program.

Should it be necessary to actually proceed to binding arbitration, our claim would be considerably in excess of that amount, since you have already derived benefit from its use via continuing to market your products that would have been cancelled without our data base. We have also not included our operational overhead, or factored in the time value of money, in our implead claim. These amounts would be appropriate should arbitration become medwasary sary

Unless we reach an agreement upon the amount and terms of payment within five working days of receipt of this notification, we plan to initiate binding arbitration.

Sincerely.

Registration Manager

Herbicides/Growth Regulators

WAD: db

454460

State Highway 690
P. O. Box 26
Greenwood, Virginia 22943

Telephone 703 456-6832

July 11, 1983

Robert J. Taylon Product Hanager 25 Fungicide-Herbicide Branch Registration Division (TS-7670) ENVIRONMENTAL PROTECTION ALENCY 401 M Street, S.W. Washington, D.C. 20460

Dear Mr. Taylor:

Bubject: KAA Registration

1-Naphthalene Acetic Acid Sodium Salt MFA Reg. No. 11546-1 1-Naphthalene Acetic Acid MFA Reg. No. 11546-2

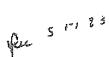
Our letver and submissions of May 23, 1983

On May 23, 1983 we sent a letter to im. James W. Akerman, with a copy to you, concerning the receipt of Mr. Akerman's letter of May 12, 1983, in which he states there are two requirements which had to be met by Greenwood Chemical Company before processing of re-registration of our products. In our letter we mentioned the fact that the manufacturing process for our products had been submitted on Greenwood letterhead rather than the "Confidential Stajement of Formula", EPA form 8570-4, and that we had received your letter of Mar. 25, 1983 in which we understood that labeling submission of changes would not be necessary until you had received and reviewed the required Acute Oral, Acute Inhalation and Dermal Sensitization studies. With our letter of May 23, 1983, we submitted the EFA form 8570-4, "Confidential Statement of Formula", and our typed revised latels. One of the purposes of this letter is to inquire of the status of our submissions and our re-registration for our products. To date, we have not heard further from EPA on this matter. Your comments would be appreciated.

The second reason for writing is to let you know that once again our customers have informed us that they were told by someone, but could not remember who, that Greenwood Chemical Company did not have their registration. As you and Greenwood Chemical Company knows this rumof is not true. If there is anything that you can do to expedite our re-registration for our products we would appreciate it. Hopefully this would put an end to all rumors. These numors are costing us business, and this we cannot afford to have happening, especially when you depend on all your customers to help keep you in business. Your help and cooperation in this matter would be appreciated. Looking forward to hearing from you.

Surfially yours,

Bashan in Februar





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

MAY 12 1983

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

Mr. Clinton C. Shipman President Greenwood Chemical Co. P.O. Box 26 State Highway 690 Greenwood, VA 22943

Dear Mr. Shipman:

I appreciated the opportunity to discuss with you the registration standard for Naphthaleneacetic Acid. As I indicated we have been working with Mr. Marc Jones, EPA Small Business Ombudsman, to provide additional guidance to you concerning the re-registration of your products.

In my review of your response to the Guidance Package for Naphthaleneacetic Acid, I find that you have not complied with two of the requirements. Before we can process the re-registration of your products we will need a revised label and a confidential statement of formula for each of the products. These should be submitted immediately.

Please send the above information to Mr. Robert Taylor, PM 25. If I can be of additional help, please let me know.

We lock forward to your response.

Sincereta

James W. Akerman, Chief Fungicide-Herbicide Branch

Registration Division (TS-767C)

(703) 557-1650

mes W.

cc: R. Taylor, PM 25 M. Jones

MITED STATES EN 900 DC 344 C.inton H. Stirman Greenwood Themical Loraphy tate " ' P.O. " x " reenate . 1 . 24 ' May 23, 1983 Jear Mr. Triman: Subjedence to Akardan didner Functed to North old of Branch Registration Division (T8-767C) ENVIRONMENTAD PROTECTION ACENCY 401 M. Street, 918; 1011 Mandage D. D. 1 15050 1 1 mary 17, an ary 31, and bestude a TR ready, Primary -omplited out wiew of the acure Dermal "". Door Hr. Akorman १४० १वर्ष ६ ३०६ the section is the second THE MO SOCIAL POOR LOWER OF May 12, 1903 on May 17, 1903 and acce have recognised our filles for the data which you do not have in BALL YEAR ESECULIVESTADO ALLOS. "your recommendation of him recommend to the second of the MA form 8570-b. Therefore, we are submitting this information for our two products. products.' qued to de the efficial forms. Please note the copy of Hr. Robert Taylor's letter compaining his statement "Labeling comments are reserved until we have received and reviewed the required Acute Oral, Acute Inhalation, and Dermal Sensitieation studios". Our unforstanding was that a revised label subsission would not be needed until Mr. Taylor's department had a chance to neview the studios entaltied for these catagories, and then he would inform as of those revisions. Evidently this was not the case, therefore, we have enclosed copies of our revised labels for 1-Rephthaless Acetic Acid and the 1-Raphthaloge Acetic Acid Scrium Salt. Those submissions should occapiete the file at this point of the inorder for our registration to be continued. If there are other 000000 requirements, please let us know as soon as you possibly can, so we 90 0 0 0 0 0 p 000000 may do what is eccessary. Registiati 1 3 00000 0 Cordially yours, 999999 12 Mil + Martal otherwise D. Zunnen leberte

202/cr

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WITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20060

OFFICE OF. PRETICAGES AND TORIC SUDSTANCES

Clinton B. Shipman Greenwood Chemical Comapny State Highway 690 P.O. Box 26 Greenwood, VA 22943

Dear Mr. Shipman:

Subject: NAA Reregistration

l-Naphthalene Acetic Acid, Sodium Salt

EPA Registration No. 11546-1 1-Naphthalene Acetic Acid EPA Registration No. 11546-2

Your Submissions of January 17, Jahuary 31,

and February 16, 1983

- We have completed our review of the Acute Dermal Toxicity Study, Primary Eye Irritation Study and Primary Skin Irritation Study. These studies are acceptable and fulfill the requirements for such studies in the NAA Reregistration Standard.

Labeling comments are reserved until we have received and reviewed the required Adute Oral, Abute Inhalation and permal Sensitization studies:

For your future reference the following EPA Accession Numbers have been assigned to the data submitted.

| yaça | • | EPA Accession No. |
|---------------------------------|---|-------------------|
| Acute Dermal Toxicity Study | | 249481 |
| Primary bermal Irritation Study | | 249319 |
| Primary Eye Trritation Study | • | 249320 |

aylor

Fungicide-Herbicide Branch

Registration Division (TS-767C)

Product Madager (35)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

JIN 24 1983

Oppice of Pesticides and Toxic Substances

Mr. Clinton B. Shipman Greenwood Chemical Co. State Highway 690 P.O. Box 26 Greenwood, VA 22943

Dear Mr. Shipman:

Subject: NAA Reregistration

1-Naphthalene Acetic Acid, Sodium Salt

EPA Registration No. 11546-1 1-Naphthalene Acetic Acid EPA Registration No. 11546-2

Your Submissions of February 25 and 28,

and April 22, 1983

We have completed our review of the Acute Oral Toxicity Study, the Dermal Sensitization Test, and the Acute Inhalation Toxicity Study. These studies are acceptable.

For your future reference, the following BPA Accession Numbers have been assigned to the data submitted.

| D | at | a | | |
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| | | | | |

EPA Accession No.

Acute Oral Toxicity Study

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Dermal Sensitization Test

249659

Acute Inhalation Study

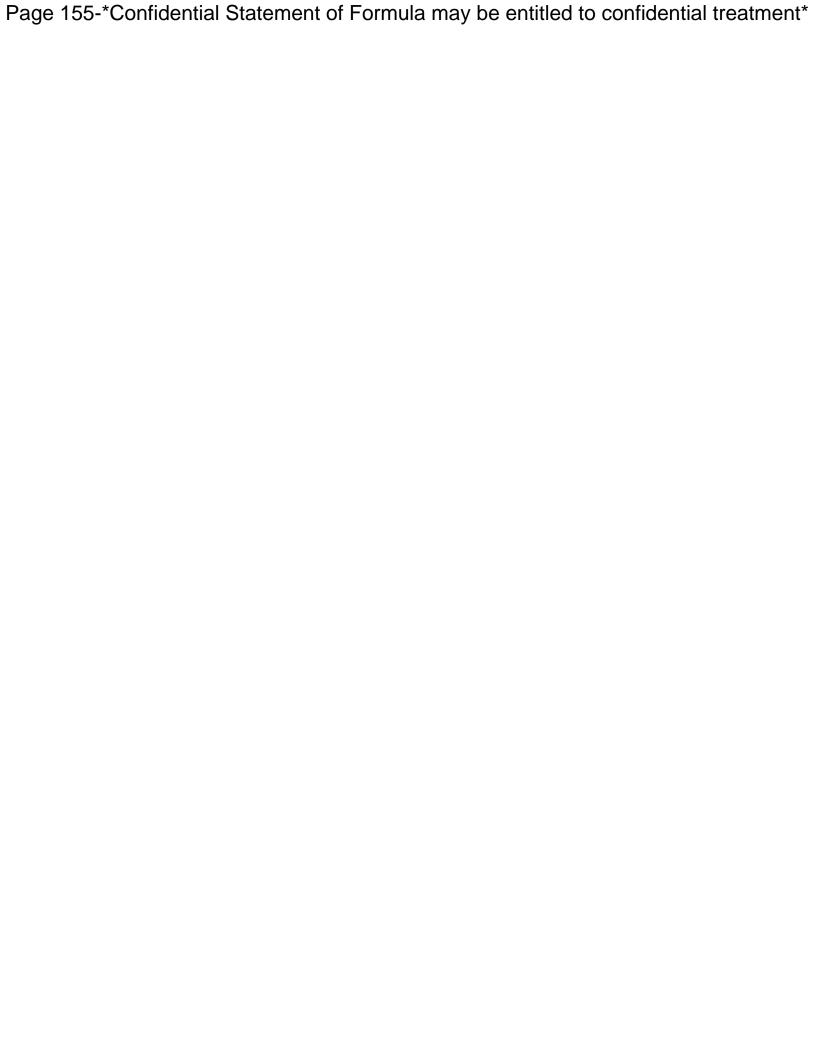
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Sincerely yours,

Robert J. Phylor

Product Manager (25

Fungicide-Herbicide Branch Registration Division (TS-767C)



A PLANT CROWTH REGULATOR FOR FORMULATING USE ONLY

| 1 | : Ingredients -Naphthalene Ingredients | A(| | | | | | | | | | | | | | | | | | |
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PRECAUTIONARY STATEMENT

MAY CAUSE IRRITATION OF NOSE AND THROAT. MAY BE HARMFUL IF SWALLOWED OR INHALED. DO NOT BREATH DUST, USE ADEQUATE VENTILIZATION. AVOID CONTACT WITH EYES, SKIN OR CLOTHING. WASH THOROUGHLY AFTER HANDLING. KEEP AWAY FROM FEED OR FOOD PRODUCTS.

STATEMENT OF PRACTICAL TREATMENT

IN CASE OF EYE CONTACT, FLOOD EYES IMMEDIATELY WITH PLENTY OF WATER FOR AT LEAST 15 MINUTES AND GET MEDICAL ATTENTION.

IF SWALLOWED, CALL A DOCTOR OR POISON CONTROL CENTER. DRINK 1 OR 2 CLASSES OF WATER AND INDUCE VOMITING BY TOUCHING BACK OF THROAT WITH CLEAN FINGER. DO NOT INDUCE VOMITING OR GIVE ANYTHING BY MOUTH TO AN UNCONSCIOUS PERSON.

IN CASE OF SKIN CONTACT. FLUSH WITH PLENTY OF SOAP AND WATER.

ENVIRONMENTAL HAZARDS

DO NOT DISCHARGE INTO LAKES, STREAMS, PONDS, OR PUBLIC WATERS UNLESS IN ACCORDANCE WITH A NPDES PERMIT. FOR GUIDANCE CONTACT YOUR REGIONAL OFFICE OF THE EPA.

DIRECTIONS FOR USE

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN ANY MANNER INCONSISTANT WITH ITS LABELING.
THIS PRODUCT MAY BE USED ONLY FOR MANUFACTURING, REPORMULATING, OR COMPOUNDING USE.

STORAGE AND DISPOSAL

PESTICIDES, SPRAY MIXTURES, OR RINSATE THAT CANNOT BE USED ACCORDING TO LABEL INSTRUCTIONS MUST BE DISPOSED OF ACCORDING TO FEDERAL, STATE, AND LOCAL PRECEDURES UNDER THE RESORCE CONSERVATION AND RECOVERY ACT.

DISPOSE OF LINERS ACCORDING TO APPROVED FEDERAL. STATE, AND LOCAL PROCEDURES UNDER THE RESOURCE CONSERVATION AND RECOVERY ACT.

DO NOT REUSE EMPTY CONTAINER, DESTROY BY PERFORATING OR CRUSHING AND DISPOSE OF IN-A SANITARY LANDFILL, OR BY INCINERATION IF PERMITTED BY STATE AND LOCAL AUTRORITIES.

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MANUFACTURED BY:

P.O. BOX 26, STATE HIGHWAY 690 GREENWOOD, VA 22943

REGISTRATION DIVISION DATA REVIEW RECORD Confidential Subtress Information -- Dose Not Contain National Statuthy Information (E.O. 12088) 24 UN 1983 1. CHEMICAL NAME 3. ACTION CODE TO BE COMPLETED BY PM 2. IDENTIFYING NUMBER 4. ACCESSION NUMBER RECORD NUMBER 1988 MAG. ED (EPA 9_PRODUCT MANAGER (PM) TO BE COMPLETED BY PCB 14. CHECK IF APPLICABLE DATE SENT TO HEOLISS ☐ Minor Use Public Health/Querantina 12. PRIORITY NUMBER Part of IPM] Substitute Chemical 13. PROJECTED RETURN DATE D Review Requires Less Than 4 Hours Sessonal Concern 15. INSTRUCTIONS TO REVIEWER F. INSTRUCTIONS c. Derso A. HED [] Total Assessment - 3(e)(5) [] (perements) Risk Assessment -3(c)(7) and/or E.L. Johnson memo of May 12; 1977. O. TES/AD E. Al-Othor B. SPAD (Send Copy of Form to SPRD PM) Chemical Undersping Active RPAR Review Chemical Undergoing Active Registration Standards Review 16. RELATED ACTIONS 稳能 18. REVIEWS SENT TO □ EF Отв 🗆 EEB OPL ☐ RCB O EFB □ erso NUMBER OF ACTIONS TYPE OF REVIEW To EUP Registration Patition mert MNA USE Other TOXICOLOGY ECOLOGICAL EFFECTS RESIDUE CHEMISTRY ENVIRONMENTAL DATE CHEMISTRY EFFICACY PRECAUTIONARY LABELING ECONOMIC ANALYSIS 24. Include an Original and 4 Ifour) Copies of This Completed Form for Each Branch Chertes 707 Review. Representative Labels Showing 23. Date Returned to AD Label Submitted Confidential Ito be completed by 20. U with Application Attached 22. 🛘 Statement of Accepted Uses HEO) Formula Review. Attached

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STORAGE AND DISPOSAL

(type size
requirements)

Do not contaminate water, food or feed by storage or disposal

STORAGE:

PESTICIDE DISPOSAL:

CONTAINER DISPOSAL:

TABLE XIII--PESTICIDE DISPOSAL STATEMENTS

HAZARDOUS WASTE

YON-HAGARDOUS WASTE

Pesticide, soray mixture, or rinse water that cannot be used according to label instructions must be disposed of according to Federal or approved state procedures under Subtitle C of the Resource Conservation and Recovery Act.

Pesticide, spray mixture, or rinse vater that cannot be used according to label instructions must be disposed of according to applicable Federal, state, . or local procedures.

TABLE XIV--CONTAINER DISPOSAL STATEMENTS

| Container Type | Disposal statement |
|----------------------------------|--|
| Metal concainers | Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other approved state and local procedures. |
| Plastic containers | Triple rinse (or equivalent). Then offer for recycling or reconditioning, or dispose of in a sanitary landfill, or by incineration if allowed by state and local authorities. |
| Glass | Triple riase (or equivalent). Then dispose of in a sanitary landfill, or by other approved state and local procedures. |
| Fiber drums with liners | Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by State and local authorities. If drum cannot be reused, dispose of in the same manner. |
| Paper and plastic bags | Completely empty bag by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of bags in a sanitary landfill or by incineration if allowed by State and local authorities. |
| Compressed gas cylinders | Return empty cylinder for reuse (or similar wording). |

l Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

thereby conserve resources, while at the same time avoiding the potential hazards associated with discarding of hazardous chemicals. The above cractices also avoid causing many tnousands of wholesalers, retailers and users from becoming generators of hazardous westes because they will be able to return the materials for reuse instead of possibly discarding them. The Agency believes that many of these persons will be unfamiliar or not well acquainted with the regulations and may fail to properly perform the responsibilities of a generator if they have to discard the materials.

It is quite likely that, in some cases, a manufacturer or supplier will find it necessary to discard some portion of the materials returned to him because he is unable to reprocess, repackage, resell or use it. Where this occurs, that portion which is discarded becomes a hazardous waste when it is discarded or when a decision is made to discard the material. In this situation the manufacturer or supplier is the generator of a hazardous waste because he is the "person...whose act.... produces hazardous waste..." (see the definintion of "generator" in § 280.10).

C. Are manufactured articles (such as battery and mercury vapor lights) that contain any of the chemicals listed in § 261.33 hazardous wastes by definition if they are discarded or intended to be discarded?

EPA intends that the materials listed in § 261.33 include only those commerical chamical products and manufacturing chemical intermediates that are known by the generic name of the chemicals listed in paragraphs (e) and (f) of that section. Manufactured articles that contain any of the chemicals listed in paragraphs (e) and (f) are rarely, if even, known by the generic name of the chemical(s) they contain and, therefore, are not covered by the § 281.33 listings. Should the Agency find it necessary to list any manufactured articles es hazardous wastes, it will initiate relemaking to add these articles to § 261.33.

Date: November 20, 1980.
Dougles M. Coetle.

Administrator.

PART 261—IDENTIFICATION AND LISTING OF HAZARDOUS WASTE

Title 40. Part 251 of the Code of Federal Regulations is amended as follows:

1. Revise § 281.33 to reed as follows: '

§ 281.33 Disearced commercial chemical products, off-specification species. containers, and spill residues thereof.

The following materials or items are hazardous wastes if and when they are discarded or intended to be discarded:

[al.Any commercial chemical product or manufacturing chemical intermediate having the generic name listed in paragraphs (e) or (f) of this section.

(b) Any off-specification commercial chemical product or manufacturing chemical intermediate which, if it met specifications, would have the generic name listed in paragraphs (e) or (f) of this section.

(c) Any container or inner liner removed from a container that has been used to hold any commercial chemical product or manufacturing chemical intermediate having the generic name listed in paragraph (e) of this section, unless:

(1) The container or inner liner has been triple rinsed using a solvent capable of removing the commercial chemical product or manufacturing chemical intermediate; or

(2) The container or inner liner has been cleaned by another method that has been shown in the scientific literature, or by tests conducted by the generator, to achieve equivalent removal; or

(3) In the case of a container, the inner liner that prevented contact of the commercial chemical product or manufacturing chemical intermediate with the container, has been removed.

(d) Any residue or contaminated soil. water or other debris resulting from the cleanup of a spill, into or on any land or water, of any commercial chemical product or manufacturing chemical intermediate having the generic came listed in persgraphs (e) or (f) of this Section. [Comment: The phrase "commercial chemical product or manufacturing chemical intermediate having the generic name listed in . , refere to a chemical substance which is manufactured or formulated for commercial or manufacturing use which consists of the commercially pure grade of the chemical, any technical grades of the-chemical that are produced or marketed, and all formulations in which the chemical is the sole active ingredient, it does not refer to a material such as a menufacturing process waste, that contains any of the substances listed in paragraphs (e) or (f). Where a manufacturing process waste is deemed to be a bazardous weste because it contains a substance listed in peragraphs (e) or (f), such weste will be listed in sither §§ 261.31 or 261.32 or will be identified as a hezardous waste by

the characteristics set forth in Subpert C of this Part.

(e) The commercial chemical products or menufecturing chemical intermediatos. Jeforted to in paragraphs (a) through (d) of this section, are centified as acute hezardous wastes (H) and are subject to the small quantity exclusion defined in § 181.3(e). Comment: For the convenience of the regulated community the primary hazardous properties of these materials have been indicated by the letters T (Toxicity), and R (Reactivity). Absence of a letter indicates that the compound only is listed for scuts toxicity.] These wastes and their corresponding EPA Hazardous Waste Numbers are:

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Appendix VIII (Amended)

2. in Appendix VIII of Part 281, delete the following compounds: Ethylezediamins

-N-Vitrosocipisenylamna

- Olayi alcohol condensed with 2 moles ethylene crude

-1-2 Propanediol

Appendix VIII [Amended]

3. In Appendix VIII of Part 281, add the following constituent alphabetically: -lee butyl alcohol

These regulations are issued under the authority of Sections 1003, 2002(a) and 3001 of the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act of 1978 (RCRA), as amended, 42 USC 6908, 6912(a) and 6921. [78 Data common First 11-2-20 km pm] called comp case-20-20.

40 CFA Part 201

(SWH-FRL 1880-6)

Hazardous Waste Management System; Identification and Listing of Hazardous Waste >

Agency. U.S. Environmental Protection Agency.

ACTION: Grant of temporary exclusions, and request for comment.

sussiant: The Environmental Protection Agency (EPA) is today temporarily excluding solid wastes generated at several particular generating facilities from hazardous waste status. These temporary exclusions respond to delisting petitions submitted under 40 CFR 260.20 and 260.22 and are granted pursuant to 40 CFR 260.22(m). The effect of this action is to temporarily exclude certain wastes generated at these facilities from listing as hezardous

wastes under 40 CFR 261, and from the management standards issued by EPA under Sections 2002 through 3000 of RCRA (40 CFR Parts 262 through 265 and 122 through 124 of this Chapter).

OATES: Effective date: November 19. 1380.

EPA will accept public comments on these temporary exclusions until january 26, 1861. Any person may request a hearing on these temporary exclusions by filing a request with John P. Lehman, whose address appears below, by December 17, 1980. The request must contain the information prescribed in § 250.20(d) of this chapter.

ADDRESSES: Comments should be sent to the Docket Clerk. Office of Solid Waste (WH-562), U.S. Environmental Protection Agency. 401 M Street. S.W., Washington, D.C. 20460.

Requests for hearing should be addressed to John P. Lehman, Director, Hazardous and Industriai Waste Division. Office of Solid Weste (WH-565), U.S. Environmental Protection Agency, Washington, D.C. 20460. Communications should identify the regulatory docket number "Section 3001/Delisting Petitions."

The public docket for these temporary exclusions is located in Room 2711. U.S. Environmental Protection Agency. 401 M St., S.W., Weshington, D.C. 20460 and is evailable for viewing from 9 a.m. to 4 p.m., Mondey through Friday, excluding holidays.

POW FURTHER IMPORMATION CONTACT: Myles Morse. Office of Solid Waste (WH-585), U.S. Ecvironmental Protection Agency, 401 M St. S.W., Washington, D.C., (202) 755-9157. SUPPLEMENTARY IMPORTATIONS OR July 16, 1960 and November 12, 1860 as part of its final and interim final regulations implementing Section 3001 of RCRA. EPA published lists of hazardous wastes from neo-specific and from specific sources. See 40 CFR §§ 281.31 and 281.32 (45 FR 47832-47836 and 74890-74692). These wastes were listed as hezardous because they typically and frequently exhibit either any of the characteristics of hazardous wastes identified in Subpart C of Part 261 (ignitability, corresivity, reactivity and EP texicity) or meet the criteria for listing contained in §§ 281.11(a)(2) or 281.11(a)(3).

The Agency, however, recognizes that individual weste streams may vary depending on raw materials, industrial processes and other factors. Thus, while a type of weste described in these regulations generally is hazardous, a specific waste meeting the listing description from an individual facility may not be hazardous. For this reason.

11546-2

May 23, 1983

James W. Akerman, Chief Fungicide-Herbicide Branch Registration Division (TS-7670) BNY IPONMENTAL PROTECTION AGENCY 401 H Street, S.W. Vashington, D.C. 20460

Dear Mr. Akeman:

We received your letter of May 12, 1983 on May 17, 1983 and have researched our files for the data which you do not have in your reregistration files.

We had substited our manufacturing process on Greenwood letterhead, not on the official "Confidential Statement of Formula", RPA form 3570-4. Therefore, we are submitting this information for our two products, on the official forms.

Please note the copy of Mr. Robert Taylor's latter containing his statement "Laboling comments are reserved until we have received and reviewed the required Acute Gral, Acute Inhalation, and Dermal Bensitization studies". Our understanding was that a revised label submission would not be needed until Mr. Taylor's department had a chance to review the studies submitted for these catagories, and then he would inform us of those revisions. Evidently this was not the case, therefore, we have enclosed copies of our revised labels for 1-Naphthalene Acetic Acid and the 1-Naphthalene Acetic Acid Sodium Salt.

These submisations should complete the file at this point of time inorder for our registration to be continued. If there are other requirements, please let us know as soon as you possibly can, so we may do what is necessary.

Cordinally yours,

NO hammatches

B. Shannon Roberts

BSR/er

Englosures: 5

co: Robert Taylor, Product Manager 25

A PLANT GROWTH REGULATOR FOR FORMULATING USE ONLY

ACTIVE INCREDIENTS: KEEP OUT OF REACH OF CHILDREN (la pt) (18 pt) CAUTION

PRECAUTIONARY STATEMENT

MAY CAUSE IRRITATION OF NOSE AND THROAT. MAY BE HARMFUL IF SWALLOWED OR INHALED. DO NOT BREATH DUST, USE ADEQUATE VENTILIZATION. AVOID CONTACT WITH EYES. SKIN OR CLOTHING. WASH THOROUGHLY AFTER HANDLING. KEEP AVAY FROM FEED OR FOOD PRODUCTS.

STATEMENT OF PRACTICAL TREATMENT

in case of eye contact. Flood eyes immediately with plenty of water for at least 15 MINUTES AND GET MEDICAL ATTENTION. IF SWALLOWED, CALL A DOCTOR OR POISON CONTROL CENTER. DRINK 1 OR 2 GLASSES OF

water and induce vomiting by Touching back of throat with clean finger. Do not INDUCE VOMITING OR GIVE ANYTHING BY MOUTH TO AN UNCONSCIOUS PERSON.

in case of skin contact, flush with plenty of soap and water.

ENVIRONMENTAL HAZARDS

do not discharge into lakes, streams, fonds, or public waters unless in accordance with a mpdes permit. For guidance contact your regional office of the epa.

DIRECTIONS FOR USE

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN ANY MANNER INCONSISTANT WITH ITS LABELING. THIS PRODUCT MAY BE USED ONLY FOR MANUFACTURING, REPORMULATING, OR COMPOUNDING USE.

STORAGE AND DISPOSAL

PESTICIDES, SPRAY MIXTURES, OR RINSATE THAT CANNOT BE USED ACCORDING TO LAREL INSTRUCTIONS MUST BE DISPOSED OF ACCORDING TO FEDERAL, STATE, AND LOCAL PROGRUMES. UNDER THE RESORCE CONSERVATION AND RECOVERY ACT. 000000

DISPOSE OF LINERS ACCORDING TO APPROVED FEDERAL, STATE, AND LOCAL PROCEDURES UNDER THE RESOURCE CONSERVATION AND RECOVERY ACT.

90000 DO NOT REUSE EMPTY CONTAINER, DESTROY BY PERFORATING OR CRUSHING AND DISPOSE OF IN % 0000 SANITARY LANDFILL, OR BY INCINERATION IF PERMITTED BY STATE AND LOCAL AUTHORITIES. 9 9 9

EPA REG. NO. 11546-2 (18 pt)

(14 pt) EPA EST 80, 31546-VAI

MANUFACTURED BY:

NET VEIGHT

GREENWOOD CHEMICAL COMPANY P.O. BOX 26, STATE HIGHWAY 690 GREENWOOD, VA 22943



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



Clinton 8. Shipman Greenwood Chemical Comapny State Highway 690 P.O. 80x 26 Greenwood, VA 22943

Dear Mr. Shipman:

Subject: NAA Reregistration

1-Naphthalene Acetic Acid, Sodium Salt

EPA Registration No. 11546-1 1-Naphthalene Acetic Acid EPA Registration No. 11546-2

Your Submissions of January 17, Jahuary 31,

and Pebruary 16, 1983

We have completed our review of the Acute permal Toxicity Study, Primary Eye Irritation Study and Primary Skin Irritation Study. These studies are acceptable and fulfill the requirements for such studies in the NAA Reregistration Standard.

Labeling comments are reserved until we have received and reviewed the required Acute Oral, Acute Inhalation and Dermal Sensitization studies.

for your future reference the following EPA Accession Numbers have been assigned to the data submitted.

| Acute Dermal Toxicity Study Primary Dermal Irritation Study Primary Eye Irritation Study Sincerely yours, Robert . raylor Product Manager (75) Pungicide-Herbicide Branch Registration Division (TS-767c) | Primary Dermal Irritation Study Primary Eye Irritation Study Sincerely yours, Robert J. Taylor Product Manager (75) Pungicide-Herbicide Branch Registration Division (TS-767c) | Data | | EPA ACC | ession N | 10. |
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| | | Primary Dermal Irritation | Sincerely yours, Robert J. Paylor Product Hanager (45) Pungicide-Herbicide Bran | 249319 249320 | | 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 |

A PLANT GROWTH REGULATOR FOR FORMULATING USE ONLY

| ACTIVE INGREDIENTS: L-NAPHTHALENE A INERT INGREDIENTS | ACE. | ric | \CI | D • | D 6 | o 0 | o | 9 | e a | ۵ • | 9 | 0 | • | o \$ | 4 | • | • | 9 | 9 | ф Ф | HUNINUH | 98.5% 1.5% | |
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PRECAUTIONARY STATEMENT

MAY CAUSE IRRITATION OF NOSE AND THROAT. MAY BE HARMFUL IF SWALLOWED OR INHALED. DO NOT BREATH DUST, USE ADEQUATE VENTILIZATION. AVOID CONTACT WITH EYES, SKIN OR CLOTHING. WASH THOROUGHLY AFTER HANDLING. KEEP AWAY FROM FEED OR FOOD PRODUCTS.

STATEMENT OF PRACTICAL TREATMENT

IN CASE OF EYE CONTACT, FLOOD EYES IMMEDIATELY WITH PLENTY OF WATER FOR AT LEAST 15 HINUTES AND GET MEDICAL ATTENTION.

IF SWALLOWED, CALL A DOCTOR OR POISON CONTROL CENTER. DRINK 1 OR 2 GLASSES OF WATER AND INDUCE VOMITING BY TOUCHING BACK OF THROAT WITH CLEAN FINGER. DO NOT INDUCE VOMITING OR GIVE ANYTHING BY MOUTH TO AN UNCONSCIOUS PERSON.

IN CASE OF SKIN CONTACT, FLUSH WITH PLENTY OF SOAP AND WATER.

ENVIRONMENTAL HAZARDS

DO NOT DISCHARGE INTO LAKES, STREAMS, FONDS, OR PUBLIC WATERS UNLESS IN ACCORDANCE WITH A NPDES PERMIT. FOR GUIDANCE CONTACT YOUR REGIONAL OFFICE OF THE EPA.

DIRECTIONS FOR USE

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN ANY MANNER INCONSISTANT WITH ITS LABELING.

THIS PRODUCT MAY BE USED ONLY FOR MANUFACTURING, REFORMULATING, OR COMPOUNDING USE.

STORAGE AND DISPOSAL

PESTICIDES, SPRAY MIXTURES, OR RINSATE THAT CANNOT BE USED ACCORDING TO LABEL INSTRUCTIONS MUST BE DISPOSED OF ACCORDING TO FEDERAL, STATE, AND LOCAL PRECEDURES UNDER THE RESORCE CONSERVATION AND RECOVERY ACT.

DISPOSE OF LINERS ACCORDING TO APPROVED FEDERAL, STATE, AND LOCAL PROCEDURES UNDER THE RESOURCE CONSERVATION AND RECOVERY ACT.

Do not reuse empty container, destroy by perforating or crushing and dispose of in a sanitary landfill, or by incineration if permitted by state and local authorities.

| pt) EPA | PA EST [°] N O °115454/ A I |
|---------|--|
| Ç | n) El |

MANUFACTURED BY:

P.O. BOX 26, STATE HIGHWAY 690 GREENWOOD, VA 22943

a plant growth regulator for formulating use only

ACTIVE INGMEDIENTS: 1-naphthalene acetic acid Minimum 98.5% KEEP OUT OF REACH OF CHILDREN (14 pt) (18 pt) CAUTION

PRECAUTIONARY STATEMENT

may cause irritation of nose and throat. May be harmful if svallowed or inhaled. DO NOT BREATH DUST, USE ADEQUATE VENTILIZATION. AVOID CONTACT WITH EYES, SKIN OR CLOTHING. WASH THOROUGHLY AFTER HANDLING. KEEP AWAY FROM FEED OR FOOD PRODUCTS.

STATEMENT OF PRACTICAL TREATMENT

In case of eye contact, flood eyes immediately with plenty of water for at least 15 MINUTES AND GET MEDICAL ATTENTION. IF SWALLOWED. CALL A DOCTOR OR POISON CONTROL CENTER. DRINK 1 OR 2 GLASSES OF WATER AND INDUCE VONITING BY TOUCHING BACK OF THROAT WITH CLEAN FINGER. DO NOT INDUCE VOMITING OR GIVE ANYTHING BY MOUTH TO AN UNCONSCIOUS PERSON. IN CASE OF SKIN CONTACT, FLUSH WITH PLENTY OF SOAP AND WATER.

ENVIRONMENTAL HAZARDS

do not discharge into lakes. Streams. Ponds. Or fublic waters unless in accordance WITH A NPDES PERMIT. FOR GUIDANCE CONTACT YOUR REGIONAL OFFICE OF THE EPA.

DIRECTIONS FOR USE

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN ANY MANNER INCONSISTANT with its labeling. this product hay be used only for manufacturing, reportulating, or compounding use.

STORAGE AND DISPOSAL

PESTICIDES, SPRAY MIXTURES, OR RINSATE THAT CANNOT BE USED ACCORDING TO LABEL INSTRUCTIONS MUST BE DISPOSED OF ACCORDING TO FEDERAL, STATE, AND LOCAL PRECEDURES..... UNDER THE RESORCE CONSERVATION AND RECOVERY ACT.

DISPOSE OF LINERS ACCORDING TO APPROVED FEDERAL, STATE, AND LOCAL PROCEDURES UNDER THE RESOURCE CONSERVATION AND RECOVERY ACT.

DO NOT REUSE ENTTY CONTAINER. DESTROY BY PERFORMING OR CRUSHING AND DISPOSE OF IN A SANITARY LANDFILL, OR BY INCINERATION IF PERMITTED BY STATE AND LOCAL AUTHORITIES. """

EPA REG. NO. 11546-2 (14 pt)

(14 pt) EPA EST NO. 11546-741

MANUFACTURED BY:

NET VEIGHT:

GREENWOOD CHEMICAL COMPANY P.O. BOX 26, STATE HIGHWAY 690 GREENWOOD. VA 22943

JM 2 4 1963

Mr. Clinton B. Snipman Greenwood Chemical Co. State Highway 600 P.O. Box 26 Greenwood, VA 22943

Dear Mr. Shipman:

Eubject: MhA Meregistration

1-Naphthalene Acetic Acid, Somium Salt

EPA Registration No. 11546-1 I-Naphthalene Acetic Acid EPA Registration No. 11546-2

Your Subaissions of February 25 and 28,

and April 22, 1983

We have completed our review of the Acute Oral Toxicity Study, the Dermal Sensitization Test, and the Acute Inhalation Toxicity Study. These studies are acceptable.

For your future reference, the following SPA Accession Numbers have been assigned to the data subsitted.

| SPA accession No. | | | | |
|-------------------|--|--|--|--|
| 249658 | | | | |
| 249659 | | | | |
| 259986 | | | | |
| | | | | |

Sincerely yours,

Robert J. Taylot
Product Manager (25 PTP
Fungicide-Herbicide Branch
Registration Division (TS-767C)

RD:RENMERS:DCR-17066:WANG-1115C:pju:Raven:479-2013:6/22/83

State Highway 690
P. O. Box 26
Greenwood, Virginia 22943

Telephone 703 456-6832

April 22, 1983

Robert J. Taylor Product Eanager 25 Registration Division (75-767-0) ENVIRONMENTAL PROTECTION ALEBOY 401 M Street, S.J. Washington, 9.5. 20460

Ace # 250086

Dear Mr. Taylor:

Reference: NAM Registration

l-Maghthalene Acetic woid Dodinu Dal:

EFA Asgistration lo. 11546-1 1-Kanhthalenc Acesic Acid SFA Asgistration lo. 11546-2

Please find encloses a copy (2) of the Inhabation Toxicity Study on 1-Maphthalene acctic Acid as performed by Bio/dynamics, inc. In New Jorsey.

As further information becomes available, we will forward it to you.

Cordially yours,

& Sharrow Roberts

DJR/sr

Unclosures: 2

REGISTRATION DIVISION DATA REVIEW RECORD Confidential Business Information - Does Not Contain National Security Information (E.O. 12065) 1. CHEMICAL NAME 2. IDENTIFYING NUMBER 3. ACTION CODE 4. ACCESSION NUMBER TO BE COMPLETED BY PM S, RECORD NUMBER 6. REFERENCE NUMBER T. DATE RECEIVED (EPA) B. STATUTORY DUE DATE 9. PRODUCT MANAGER (PM) TO, PM TEAM NUMBER TO BE COMPLETED BY PCS 14, CHECK IF APPLICABLE 11, DATE SENT TO HED/TSS Minar Use Public Health/Quarantine 12, PRIORITY NUMBER Part of IPM L Substitute Chemical 13. PROJECTED BETURN DATE Seasonal Concern Review Requires Loss Than 4 Hours 15. INSTRUCTIONS TO REVIEWER F. INSTRUCTIONS C. Defso Total Assessment - 3(c)(6) A. HED D. TSS/RD Incremental Risk Assessment -3(c)(7) and/or E.L. Johnson memo of May 12, 1977. t. Dother B. SPRD (Send Copy of Form to SPRD PM) Chemical Undergoing Active RPAR Review Chemical Undergoing Active Registration Standards Raview 16. RELATED ACTIONS 3(c)[1](D) 18. REVIEWS SENT TO ⊐тв □ EF [PL II ECB Use Any or All Available Information Use Only Attached Data Use Only the Attached Data for Permulation and Any or Ali Available Information on the Technical or Manufacturing Chemical. □ cn RCB E BESS L EFE NUMBER OF ACTIONS TYPE OF REVIEW 19. То EVP SI.N Registration Petition Sec. 18 Inacci MNR. USF Other TOXICOLOGY **ECOLOGICAL EFFECTS** RESIDUE CHEMISTRY **ENVIRONMENTAL DATE** CHEMISTRY EFFICACY PRECAUTIONARY LABELING ECONOMIC ANALYSIS Representative 22. According 23. Date Returned to AD 24. Include an Original and 4 (four) Copies of This Completed Form Label Submitted Confidential (to be completed by with Application . Statement of for Each Branch Checked for Accepted Uses HEDI Attached Formula Attacoesi Review.

FOR FALL OFTO to JOH.

June 13, 1983 Date:

Subject: EPA Registration No. 11546-2

1-Naphthalone Acetic Acid

EPA Registration No. 11546-1

1-Naphthalene Acetic Acid, Sodium Salt

From:

Deloris F. Graham PAN 6 19 147
FHB/TSS

Robert Taylor

To:

Robert Taylor

Product Manager (25)

Applicant: Greenwood Chemical Company

P.O. Box 26

Greenwood, VA 22943

Active Ingredient:

1-Naphthaleneacetic Acid............. 98.5%

Background: Submitted Acute Inhalation Study to fulfill acute toxicity data requirements for conditional registration. Study conducted by Bio/dynamics. Inc. Data under Accession \$250086. Combined alternate and Cite-all method of support.

Recommendation:

- 1. FHB/TSS finds this study acceptable to support conditional registration of this product.
- 2. The appropriate toxicity category for this study is III CAUTION.

Label:

 The statement "Harmful if inhaled. If inhaled, remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-tomouth. Get medical attention must be included in precautionary statements.

Review:

1. Agute Inhalation Toxicity Study: Bio/dynamics, Inc.; Project No. 82-7621; March 31, 1983.

Procedure: Five male and five female Spraque-Dawley rats weighing between 235 and 297 g were exposed for four hours to a mean analytical concentration of 0.45 mg/l (nominal concentration = 15 mg/l). Average mass median aerodynamic diameter was 3.1 microns and average geometric standard deviation was 4.2. Mean chamber temperature 71°P and relative humidity 62%. Observations were made for 14 days after exposure. Mecropsy performed on all animals.

Results: No mortalities. Toxic signs included closed eyes, wet and matted fur, dried material on the fur and huddling, swollen eyelids, dry rales, dried material on the forepaws, yellow or brown anogenital fur, dried material around the facial area, lacrimation, mucoid nasal discharge, red nasal discharge, salivation, chromodacryotthea, labored breathing. Necropsy revealed discolored lungs, surface irregularities, renal discoloration and dilated renal pelves in some of the animals. LC50 greater than 0.45 mg/l gravimetric concentration.

Study Classification: Core Guideline Data.

Toxicity Category: III - CAUTION

APR 28 1983

MEMORANDUM

Marc Jones, EPA Small Business Ombudsman Office of Policy and Resource Management (PM-220)

SUBJECT: Fact Sheet on the Greenwood Chemical Company

I am attaching for your information a fact sheet on the Greenwood Chemical Company. After you have had an opportunity to look it over, call me if you have any questions.

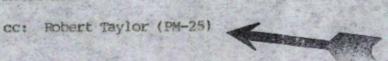
I note with some interest that he asks you to help him with his labeling. I assume he is referring to the current action we have which involves the reregistration of his two products. As you can see from items 9 and 10 in the fact sheet, the company has complied with all necessary requirements except to submit a confidential statement of formula and revised labeling for each product. The issue surrounding his negotiations with Union Carbide regarding their sharing arrangements on the cost of producing the long term data requirements identified in the registration standard does not stand in the way of our reregistering his two products. You may wish to make that clear to him.

If, however, he understands that and he still has a problem with the two missing elements (statement of formula and revised labeling) then you should ask him to get in touch with the product manager for his products, Robert Taylor (703-557-1800).

I hope this is sufficient for you to close your record on Greenwood.

> Robert V. Brown; Deputy Director Registration Division (TS-767)

Attachment



FACT SHEET

Ragistrant: Greenwood Chemical Co.

<u>Pesticide</u>: Naphthaleneacetic acid

- 1. Greenwood has two products containing naphthalene acetic acid, both registered in 1971.
- The EPA issued the registration standard for naphthaleneacetic acid (NAA) on Aug. 18, 1981.
 Standard required registrants of NAA to fill specific data gaps in order to continue registration.
- Greenwood requested a data exemption on November 6, 1981, based on the safe history of use. EPA turned down the request on Nov. 24, 1981.
- 4. On March 19, 1982, Greenwood submitted a second data waiver request, citing limited sales and history of use. However, Union Carbide, another manufacturer of NAA, has agreed to generate the required data.
- 5. On October 1, 1982, EPA sent Greenwood a notice of intent to suspend registration. On November 16, 1982, EPA withdrew the suspension because the Agency had not responded to the previous waiver requests from Greenwood.
- 6. On January 17, 1983, Greenwood submitted acute toxicity data for NAA. EPA reviewed and found the data acceptable.
- 7. Greenwood has submitted numerous copies of correspondence with Union Carbide detailing negotiations to arrive at a fair price for sharing the costs of developing the chronic data.
- 8. The Agency has had numerous phone conversations with Mr. Shipman, President of Greenwood, concerning data compensation. Mr. Shipman has complained that Union Carbide is unreasonable in it's financial demands for data sharing. The Agency has repeatedly pointed out to Mr. Shipman that it has no authority to enter into or influence such financial negotiations, and that 3(c)(1)(D) of the FIFRA, as amended, states that where registrants, failing to agree on how costs will be

shared, may initiate binding arbitration proceedings with the Federal Mediation and Conciliation Service.

- 9. Neither of the Greenwood products have been re-registered yet. Greenwood has complied with all the requirements for re-registration except the submission of confidential statements of formula and revised labeling.
- 10. Greenwood has until mid-May to satisfy the requirements mentioned above. If not satisfied the Agency would initiate a suspension action against both of the NAA products.
- 11. Complicating this whole data issue is the recent judgement (Monsanto v. Acting Administrator) which enjoined the Agency from "implemention and enforcement, in any manner, directly or indirectly, of Sections 3(c)(1)(D), 3(c)(2)(A), 10(b) and 10(d) of FIFRA. This judgement, as now interpreted, would preclude the Agency from taking any action based upon the NAA Registration Standard.

| 90 day Requirements | Submitted | Net Submitte |
|---|-----------------------------|--------------|
| FIFRA Summary Sheet Nathuchmed | × | |
| , Willingness to Enter Agreement | × | |
| Somoth Requirement 1. CSF 2. Data Comp. Statement 3. Frod. Spec. Data Report | ★ ★ | X |
| 4 Prod. Spec. Pata | * | |
| 5. Labelling | | * |
| 8 mid- Hong-term data 7. Short term data | | * |
| acute oral | * | |
| acute dermul | × | |
| grimary eye | × | |
| general skin acute inhalation dermal sensitization | X Submitted 4/20/83 X | |
| fish LC40 | , | X |
| acute tox to aquatic invert | | × 178 |

*

12 month

Dissociation vata (RCB) Each A.I.

18 month

Ternlogenicity (Tech grade of A.I)

Residue Data: (Representative Fermulation)

Craps - Apples Pears Pineapples Olives

11546-1 NAA, Sodium Sally (98.5%) & Technicalo

8/18/81 NAA Standard Issued, Oreenwood

11/2/81 + 11/0/81 - Generic Date Enempton, FITSA 11/24/81 - not eligible for Summary sheet, claiming minor-used generic data exemption

2/5/82 - FIFRA Summary, Willingness to 12/18/82 - acknowledged veceipt Inter Agreement" - (no firms cited)

3/19/82 - letter to Johnson - Taylor dala waiver request for acutes. "Product Specific Lodge Regard. Complained Union Carbide asking too much compensation.

4/23/82 letter from Compt -Suggested Errenand Schedule meeting with PA HAKerman to disease dana waiver, data comp + minor use issue.

6 82 - memorandum of meeting 10/1/82 on May 27,1982 of Adamsezyk.

Notice of Intent to Suspend

10/6/82 Questioning why swo netical no responde on waiter request

10/7/82 - requesting meeting 10/25/82 - Objection to data 10/7/80 - problems negotiating of UC. Warver request - no basis 1927/82 - problems with negotiations with Union Carbide

10/28/82 - Study gratocals for Muter

19982 - problems of neger w/ U.C. submitted Compensation & Willingingary, to Enter Agreement forms
one page fish studies.

11/29/82 from returned -

Missingard suspension campt disregard suspension notice
due to writer request. However,
noted that waiver was denied
and they must comply.

11/30/82 - Protects acceptable

10/0/82 - asked about protocols.

still rec. no response from U.C. on

compensation. Resubmitted Data

Compensation Statement & Willingness

. Statement listing Union Carbide

os not accepting their offer.

January - Peb. -

- Acuse studies submitted (except

inherlation)

- Many letters about negotiation

with U.C.

\$183 -asked for updated deta

3/23/83 - 3668 studies

no longer organised
(u.c. stagranted waiver)

State Highway 690 P. O. Box 26

Robert J. Taylor Product Manager 25 Registration Division (73-767-0) ENVIRONMENTAL PROTECTION ACCESSY 401 M Street, 3.W. Washington, U.C. 20460

Dear Mr. Taylor:

Ref: NAA Registration

Herry Le resolver. 1-haphthalene Acetic Acid Sodium Salt

BPA Registration No. 11545-1 1-Marhthalene Acetic Acid LPA Registration No. 11546-2

On March 11, 1983 I wrote you concerning registration of 1-Naphthalone Acetic Acid. We have now obtained information from Bioassay Corporation concerning the test that needs to be performed. Enclosed is a comparison of the price range submitted by Bioassay, Union Carbide's actual cost, and Union Carbide's estimated replacement cost.

We are now prepared to notify Union Carbide and request another meeting. Before we make contact, we would appreciate you informing us just how the PR NOTICE 83-1 affects our situation with Union Carbide, and how we should proceed with the situation.

Cordially yours,

Clinton C. Shipman,

President

005/bsr

Enclosure

cc: Kevin Braumber, SBA Marc Jones, 314 Warren Davis. Union Carbide

State Highway 690 P. O. Box 26

Greenweed, Virginia 2294

Telephone 703 456-6832

| Test | union care est. repl. | | union carbide actual cost | PRICE RANCE SUBMITTED BY BIOASSAY CORP. |
|--|--------------------------|--------------------|------------------------------|---|
| 163.82~1 Subchronic Oral Toxicity | | 0,000 0,000 | 29,110 67,000 | 62,000 - 75,000 ^a 55,000 - 65,000 ^b 9,000 - 11,000 ^c |
| 163.83-3 Teratology | | 95,000 60,000 | 7,400 50,000≄ | 23,000 - 26,000 29,000 - 33,000 |
| Residue | 7 | ¹⁴ °333 | 72,368 | |
| 163.84-2 163.84-3 163.84-4 Mutagenicity | 2 | 9,700 | 18,425 | Ames test 850 gach 5,000 - 8,200 3,500 - 4,500 e 3,500 |
| 163.161-1 Hydrolysis or Dissociation | 2 | 22,000 | 21,847 | |

| ₩ | Estimated | Cost | 223 | Study | in | Progress |
|---|-----------|------|-----|-------|----|----------|
|---|-----------|------|-----|-------|----|----------|

| 6.9 | Poncing |
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- a Gavago Administration
- b Dose Feed Administration
- c 14 Day Range Finder
- d Chinese Hamster Ovary Cytotoxicity Test
- e <u>In Vitro</u> Cytogenetics
- f Sister Chrometid Exchange

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State Highway 690
P. O. Box 26
Greenwood, Virginia 22943

Telephone 703 456-6832

April 5, 1983

Robert J. Taylor Product Manager 25 Registration Division (TS767-C) ENVIRONMENTAL PROJECTION AGENCY 401 M. Street, S.W. Washington, D.C. 20460

Dear Mr. Taylor:

I understand that the cite-all method of data support is no longer required in order to secure reregistration under my pending application for 1-Naphthalene Acetic Acid, identified as registration number 11546-2 and submitted on November 6, 1981. I hereby choose the alternate or combined alternate and cite-all method of data support. I have already submitted all the required data compensation forms for that method of support.

We are in discussion with Union Carbide on compensation, if we choose to go that route. We are waiting on development from EPA and their new approach to the implementation of FIFRA sec. $\Im(c)(1)(D)$.

Cordially yours,

Clinton C. Shipman

President

CCS/bsr

Appril 6, 1983

Verron A. Devis
Registration Estagor
Herbicides/Growth Regulators
UNION CARBIDZ AGRICULTURAL PRODUCTS COMPANY, INC.
P.O. Box 12014
Research Triangle Park, N.O. 27709

Dear Mr. Davis:

Your letter was written March 4, mailed on March 8, and received by us on March 10, 1983, copy enclosed. We have been in correspondence with MFA on a few matters concerning the reregistration of our labels.

We are now weiting for their response to the question before them, and the reply to the new approach on the implementation of the FIFRA, as outlined in their PR Notice 83-1, dated February 17, 1983 and received by us March 12, 1983. We sincerely hope we will get a reply from EPA in the near future.

Cordinally yours,

Cidaton G. Shipman

President

CCS/ber

oc: Robert J. Taylor, Product Hazager, RPA

July 1981

Table 3.--Benzenoid intermediates: U.S. general imports entered under schedule 4, pt. 1B, of the TSUS, by competitive status, 1/ 1980--continued

| Stat | us: Intermediates | : Quantity |
|------------|--|-----------------------|
| | : | : (pounds) |
| | : | 8 |
| | 1 | ‡ |
| | : Methyl-3,4-dimethoxy-6-nitrobenzoate | : 8,889 |
| | : 4,4'-Methylenebis(2-methylcyclohexylamine) | : 390 |
| 1 | : 4,4%-Methylenediamiline | : 493,99 |
| | : Methyl formylphenylacetate | 118,74 |
| 2 | : 2-Nethylindoline | : 3.96 |
| 3 | : 1-Methyl-2-phenylindole | 18,92 |
| 4 | : 5-Methyl-3-phenyl-4-isoxazolecarboylic acid | : 22 |
| <u>-</u> | : chloride. | |
| 2,3 | : 3-Methyl-1-phenyl-2-pyrazolin-5-one (Develor | per Z) : 262,448 |
| | : Methyl phenyl sulfide | : 44 |
| 3 | · Nethylpiperidine | : 8,44 |
| 3 3 | · N-Methyl-2-pyzrolidone | : 22,17 |
| 3 2 | : 2-Methylzesozcinol | 3,85 |
| | | 22,04 |
| 2 | : c-Methylstyrene | |
| 2 | : 2-Methylsulfonyl-4-nitroaniline | 5,19 |
| 3 | : N-Methyltetrachlorophthalimide | : 66 |
| 3 | : 3-Methylthiophene | \$7,73 |
| 2 | : 3-Methyl-1-p-tolyl-2-pyzazolin-5-one | : 27,57 |
| 3 | : Metzizanide | 3 |
| 3 | : Mixtures, industrial organic chemicals | 29,707,67 |
| 3 | : Molloplast | 520 |
| • | ' 1-Raphathalanesulfonic acid, sodium salt | 22 |
| 1 | : 1-Xaphthaleneacetic acid | 11,46 |
| 3 | : 1.8-Naphthalenediamine | : 19,52 |
|) | : 1.5-Naphthalenediol | : 1,58 |
| 2 | : 2,3-Naphthalenediol | 6,014 |
| 2 | : 1.5-Naphthalenedisulfonic acid | : 1.019 |
| 1,2 | : 2.7-Naphthalenedisulfonic acid | 92,981 |
| 1.2 | : 2.7-Kaphthalenedizulfonic acid, disodium sa | 9 |
| 3 | : Naphthalene, refine | : 9000 116, 825 |
| | : 2-Kaphthalenesulfonic acid, sodium salt | : 000 5, 73 |
| 2 | : 1,3,6-Naphthalenetrisulfonic acid | ઃ ° 22.6્રા |
| 2 | : 1.3.6(and 1.3.7)-Naphthalenetrisulfonic acid | 1, : 16.0 <u>0</u> 15 |
| | : sodium salt. | : 3000 |
| 2.3 | : Naphthalic anhydrida | : 200000 197, 528 |
| 2 | : Naphthaline-1-sulfonic acid | 27999 |
| 1,2 | : 1-Naphthoic acid | : 5.379 |
| 2 · | : 2-Naphthoic acid | |
| | | 9 9 |
| S | ee footnotes at end of table. | ଚ୍ଚୁ ତ ତ ୍ତ୍ର ଓଡ଼ |
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State Highway 690 P. O. Box 26 Greenwood, Virginia 22943

Telephone 703 456-6832

March 29, 1983

Robert J. Taylor Product Manager (25) Registration Division (TS-767C) ENVIRONMENTAL PROTECTION ACENCY 401 M Street, S.W. Washington, D.C. 20460

Dear Sir:

Reference: Registration of 1-Kaphthalene Acetic Acid

Is it possible to find out the location of Union Carbide's EPA Establishment number 264-MO-01?

we have been informed that 1-Naphthalene Acetic Acid is being manufactured by We know that 11,460 pounds of NAA was imported in 1980 and 4,400 pounds was imported in 1981, according to the "Imports of Benzenoid Chemicals and Froducts", copies enclosed. This information will help us should we go into arbitration with Union Carbide on the compensation regulation by EPA.

We would, also, like to know where we may obtain a copy of the labels for 1-Naphthalene Acetamide and the Ethyl Ester of 1-Naphthalene Acetic Acid. It is our understanding that we can use data accumulated for NAA and apply for registration for these two products. Please advise.

Cordially yours,

Clinton C. Shipman

President

CCS/bsr

Enclosures:

TECHNICAL NAPHTHALENEACETIC ACID

A PLANT GROWTH REGULATOR FOR FORMULATING USE ONLY.

ACTIVE INGREDIENT:

1-NAPHTHALENEACETIC ACID MINIMUM 95.0% INERT INGREDIENTS:

KEEP OUT OF REACH OF CHILDREN

DANGER

PRECAUTIONARY STATEMENTS

DANGER. CORROSIVE, CAUSES IRREVERSIBLE EYE DAMAGE. WEAR SAFETY GOGGLES WHEN HANDLING. HARMFUL IF SWALLOWED. AVOID CONTACT WITH SKIN AND EYES.

STATEMENT OF PRACTICAL TREATMENT

IN CASE OF EYE CONTACT PLOOD EYES IMMEDIATELY WITH PLENTY OF WATER FOR AT LEAST 15 MINUTES AND GET MEDICAL ATTENTION. IF SHALLOWED, CALL A DOCTOR OR POISON CONTROL CENTER. DRINK 1 OR 2 GLASSES OF WATER AND INDUCE VOMITING BY TOUCHING BACK OF THROAT WITH FINGER. DO NOT INDUCE VOMITING OR GIVE ANYTHING BY MOUTH TO AN UNCONSCIOUS PERSON. IN CASE OF SKIN CONTACT, FLUSH WITH PLENTY OF SOAP AND WATER.

ENVIRONMENTAL HAZARDS

DO NOT DISCHARGE INTO LAKES, STREAMS, PONDS, OR PUBLIC WATERS UNLESS IN ACCORDANCE WITH A NPDES PERMIT. FOR GUIDANCE CONTACT YOUR REGIONAL OFFICE OF THE EPA.

STORAGE AND DISPOSAL

AVOID CONTACT WITH OTHER PESTICIDES, SEEDS, FERTILIZERS OR FEED STUFFS. DO NOT USE IN EQUIPMENT OR IN CONTAINERS IN WHICH YOU HAVE HANDLED OR WILL HANDLE OTHER AGRICULTURAL CHEMICALS UNLESS THOROUGHLY CLEANED.

PESTICIDE, SPRAY MIXTURE, OR RINSE WATER THAT CANNOT BE USED ACCORDING TO LABEL INSTRUCTIONS MUST BE DISPOSED OF ACCORDING TO APPLICABLE FEDERAL, STATE, OR LOCAL PROCEDURES.

COMPLETELY EMPTY LINER BY SHAKING AND TAPPING SIDES AND BOTTOM TO LOOSEN CLINGING PARTICLES. EMPTY RESIDUE INTO EQUIPMENT. THEN DISPOSE OF LINER IN A SANITARY LANDFILL OR BY INCINERATION IF ALLOWED BY STATE AND LOCAL AUTHORITIES. IF DRUM CANNOT BE REUSED, DISPOSE OF IN THE SAME MANNER.

INSTRUCTIONS FOR FORMULATION

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING.

THIS PESTICIDE MAY BE USED ONLY FOR THE FORMULATION OF A PLANT GROWTH REGULATOR, FORMULATORS USING THIS PRODUCT ARE RESPONSIBLE FOR OBTAINING EPA REGISTRATIONS FOR THEIR FORMULATED PRODUCTS.

DISTRIBUTED BY:

UNION CARBIDE AGRICULTURAL PRODUCTS COMPANY, INC. P.O. BOX 12014, T.W. ALEXANDER DRIVE RESEARCH TRIANGLE PARK, NC 27709

EPA EST. NO. 264-NO-01

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EPA REG. NO. 264-372

"(cc) Weed.-The term 'weed' means any plant which grows where not

wanted.
"(dd) Establishment.—The term 'establishment' means any place where a pesticide or device or active ingredient used in producing a pesticide is

produced, or held, for distribution or sale.

"(ce) To Use Any Registered Pesticide in a Manner Inconsistent With Its Labeling. —The term 'to use any registered pestiscide in a manher inconsistent with its labeling' means to use any registered pesticide in a manner not permitted by the labeling: Provided, That the term shall not include (1) applying a pesticide at any dosage, concentration, or frequency less than that specified on the labeling, (2) applying a pesticide against any target pest not specified on the labeling if the application is to the crop, animal, or site specified on the labeling, unless the Administrator has required that the labeling specifically state that the pesticide may be used only for the pests specified on the labeling after the Administrator has determined that the use of the pesticide against other pests would cause an unreasonable adverse effect on the environment.
(3) employing any method of application not prohibited by the labeling, or (4) mixing a pesticide or pesticides with a fertilizer when such mixture is not prohibited by the labeling: Provided further, That the term also shall not include any use of a pesticide inconformance with section 5, 18, or 24 of this Act, or any use of a pesticide in a manner that the Administrator determines to be consistent with the purposes of this Act: And provided further. That after March 31, 1979, the term shall not niclude the use of a pesticide for agricultural or forestry purposes at a dilution less than label dosage unless before or after that date the Administrator issues a regulation or advisory opinion consistent with the study provided for in section 27(b) of the Federal Pesticide Act of 1978, which regulation or advisory opinion specifically requires the use of definite amounts of dilution.

7 LISC 136s, 136p, 136v

7 USC 1364-4 note

P LINE 1260

"SEC. 3, REGISTRATION OF PESTICIDES.

"(a) Requirement.—Except as otherwise provided by this Act, no person in any State may distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive and (having so received) delivery or offer to deliver, to eary person any pesticide which is not registered with the Administrator.

"(b) Examplions.—A passicide which is not registered with the Administrator may be transferred if—

"(1) the transfer is from one registered establishment to another registered establishment operated by the same producer solely for packaging at the second establishment or for use as a constituent part of another pesticide produced at the second establishment; or

"(2) the transfer is pursuant to and in accordance with the requirements of an experimental use permit.

"(c) Procedure for Registration.-

(1) Statement required.—Each applicant for registration of a pesticide shall file with the Administrator a statement which includes—

"(A) the name and address of the applicant and of any other person whose name will appear on the labeling:

(B) the name of the pesticide;

"(C) a complete copy of the labeling of the pesticide, a statement of all claims to be made for it, and any directions for its use;

(D) except as otherwise provided in subsection (c)(2)(D) of this section, if requested by the Administrator, a full description of the tests made and the results thereof upon which the claims are based, or alternatively a citation to data that appears in the public literature or that previously had been submitted to the Administrator and that

92 Stat. 826

Fourier 2(b) of the Federal Peuicide Act of 1978 provides. The amendment to exciton MeNIND) of the Federal Insecticide. Fungicide, and Rodenticide Act made by this section shall apply with respect to all applications for registration approved after September 30, 1978.

United States **Environmental Protection** Agency

Office of Pesticide Programs Weekington DC 20460

November 1978

OPA 17/0

The Federal Insecticide, Fungicide, and Rodenticide Act as Amended

Public Law 92-516:...: October 21,:1972::::: as amended:by Public Law 94-140 November 28, 1975 and Public Law 95-396 September 30, 1920

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1,3,6(and 1,3,7)-Naphthalenetrisulfonic acid, sodium

7-Naphthoic disulfonic acid, sodium salt - - - - - - :

Waphthalic anhydride - - -

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2,976

9,252

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FACT SHEET

Segistract: Greenwood Chemical (c.

Pesticide: Naphthaleneacetic acid

- Greenwood has two products containing maphthalene aretic acid, both registered in 1971.
- 7. The APA issued the registration standard for neghtnatempacetic sold (UAA) on Aug. 18, 1981. Standard required registrants of CAA to till specific data gays in order to continue registration.
- 3. Grewower: Chemical Co. requested a data examption on Movember 6, 1921, lased on the safe history of use. FPA turned down the request on Mov. 24, 1981.
- 4. On Nerci 19, 1982, Openhand themical submitted a second rata warver togest, citing limited sales and history of use. Powever, Union Carbids, another manufacturets or MVA, has agreed to generate the orguined data.
- 5. On October), 1982, NPA sent Grander's notice of intent to suspend registration. On Accommer 16, 1982, PPA withdraw the suspension because the Agercy had not responded to the provides waiter requests from Grandeocc.
- 6. On January 17, 1903, Greenwood submitted acute toxicity cats for CAA. SPA m views and found the data acceptable.
- 7. Although Greenword ran estimated the acute data requirements, the charmic and suf-charmic outs are still recessary to support rerequetration. Greenword has submitted numerous copies or correspondence with Daton Carbice detailing projectionies to surise at a tair prior con staring the crets of developing the erroric outs.
- The Pyoncy has had new your part conversations with Pr. Shipmen, Provident of Grecowcoo, concerning onto compensation. Pr. Shipmen has complained that thien carried is unreasonable in it's financial persons for onto sharphe. We have repeatedly pointed out to Mr. Shipmen that the Agency has no authority to unter into or insurance such transial negotialisms, and shat 3(c)(1)(D) or the EJERA, as amondor, stable that a global saling to agree on

on sharing costs may enter into binding arbitration proceedings with the Federal Mediation and Conciliation between

4. The two Greenwood products are still registered pending resolution of the data issue and compliance with the registration standard for NAA.

MK 28 1983

Clinton C. Shipman Greenwood Chemical Co. State Bighway 690 P.O. Box 26 Greenwood, VA 22943

bear Br. Shipman:

Subject: NAA Reregistration

1-daphthalene Acetic Acid

EPA Registration Number /1596-2

Inis acknowledges receipt of your letter dated March 11, 1983. The information submitted has been included in our files.

Sincerely yours,

Robert J. Taylor
Froduct Manager (25) FVC
Fungicide-Herbicide Branch
Registration Division (TS-707c)

TS-767:R.TAYLOR: DCR-25398: WANG-3336C: vgr: Raven: 479-2013:3/25/33

| | CONCURRENCES | | |
|------------------------|---|----------|--------------------|
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| STISNAME. | | | |
| DATE | | | |
| EPA Foun 1320-1 (4-81) | 1 + 2 c c c c c c c c c c c c c c c c c c | <u> </u> | OFFICIAL FILE COPY |

Clinton C. Shipman Greenwood Chemical Company State Highway 690 P.O. Box 26 Greenwood, VA 22943

Dear Mr. Shipman:

Subject: NAA Reregistration

1-Naphthaplene Acetic Acid Sodium Salt

EPA Registration No. 11546-1 1-Naphthalene Acetic Acid EPA Registration No. 11546-2 Your Letter of February 28, 1983

In response to your questions about a Union Carbide technical NAA, our records indicate that their Technical Naphthaleneacetic Acid, EPA Registration No. 264-372 was registered on August 17, 1982. A copy of the label is enclosed.

In response to the second paragraph of your letter concerning possible violations, we refer you to the Enforcement Division. Mailing address:

A. E. Conroy II, Director Pesticides and Toxic Substances Enforcement Division (EN-342) Environmental Protection Agency 401 M Street, SW Washington, D.C. 20460

The Data Requirement Charts dated July, 1981, that you have enclosed in your letter are the latest charts available. However, the following Ecological Effects studies are no longer required in connection with the NAA Reregistration Standard:

163.122-1 Effects on Terrestrial Macrophytes 163.122-2 Effects on Aquatic Macrophytes 163.122-2 Effects on Algae.

Sincerely yours,

Robert J. Paylor
Product Manager (25) FUK
Fungicide-Herbicide Branch
Registration Division (TS-767C)

RD:REMMERS:DCR-25315:WANG-3176C:mbd:Raven:479-2013:3/18/83

State Highway 690 P. O. Box 26 Greenwood, Virginia 22943

Telephone 703 456-6832

February 28, 1983

Robert J. Taylor Product Manager 25 Registration Division (TS767C) ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Dear Mr. Taylor:

Subject: 1-Naphthalene Acetic Acid Sodium Salt

EPA Registration No. 11546-1 1-Naphthalene Acetic Acid EPA Registration No. 11546-2

According to the information we received from the Initiation of Reregistration Process for Pesticide Products containing NAA, the Standards Package, and the Guidance Package issued by the Registration Division of EPA, Union Carbide Agricultural Company had only registration for their formulated products containing the 98% technical NAA, but we could not find registration for the 98% technical NAA. If this is the case, would you please infrom us to the actual date that Union Carbide received registration for the 98% technical NAA and its derivatives, if they have actually done so?

We would, also, like to know if importation of Naphthalene Acetic Acid and its derivatives made before receipt of registration of 98% NAA were made, would this be in violation of EPA rules and regulations concerning importaion? Would this violation apply to resale as well as use in formulations of the imported NAA and its derivatives, if indeed it would be concidered a violation

Enclosed please find a copy of the latest DataRequirements Charts for the registration of Naphthalene Acetic Acid and its derivatives. This copy is dated July, 1981. Any current information you may be able to send to us aid in reregistration of our products would be appreciated.

We will be looking forward to receiving the requested information

Cordially yours.

Clinton C. Shipman

President

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rese tota frequirements ore his tert es et Jura, 1981. Refer to the quidance passage for applicable frequirements.

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LALL tepurities and there is no termical chemicals produced by or for Greenwood Chemical Company, Williamter Onya Corporagion and Acoto Chemical Company when to identified, Formulations of all other technical products and chemicals covered by this Standard must be identified.

2.Complete information run: to supplied by each manufacturer on the present manufacturing process, including data listed in 43 FR 29709.

). The usper and lower limits of each extine and insert ingredient in manufacturing-use and con-use products and to declared and contribution product must be provided. If not already closered, all insert impredients among in modulate with look uses was to closered by the requirement with the Aministration.

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Pose date requirements are current as of June, 1941. Refer to the quidence excesse for undated requirements.

- Despendention date invitors that restrict in plants of eater, salts and ecotomide of WA despende residing to residence of WA and that those seldence or of the send offer of memoritate as those characters date or required to configure the despendence of these characters.
- Links does us for the committee changes intended for use on food groups only.
- J. Data on the dissociation or hydrolycation of these chemicals must be dissisted.

July, 1984

DATA REQUIREMENTS CHART A

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July. 1901

State Highway 690
P. O. Box 26
Graenwood, Virginia 22943

Telephone 703 456-6832

March 11, 1983

Robert J. Taylor Product Manager (25) Registration Division (TS767C) ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Dear Mr. Taylor:

Subject: 1-Naphthalene Acetic Acid Sodium Salt EPA Registration No. 11546-1 1-Naphthalene Acetic Acid EPA Registration No. 11546-2

We are now negotiating with Union Carbide Agricultural Products Company, which is required by law, as far as paying compensation to them.

Before we commit ourselves to paying compensation, we would like to see the technical data. Does EPA supply that data, or do we have to obtain it from Union Carbide? Your prompt reply would be appreciated.

Cordially yours,

Clinton C. Shipman,

President

CCS/bsr

I called Mr. Shipmon, told him in the would have to go through FOI or Union Carticle. Also told him legal questions concerning to clata companion deal go to OFC. The or

State Highway 690 P. O. Box 26 Greenwood, Virginia 22943

Telephone 703 456-6632

March 11, 1983

Robert J. Taylor Product Manager 25 Registration Division (TS767C) ENVIRONMENTAL PROTECTION AGENCY 401 M Street Washington, D.C. 20460

REFERENCE: Union Carbide

Dear Mr. Taylor:

Enclosed please find a copy of a letter we received from Union Carbide on January 12, 1983, and also, copy of a letter we received March 10, 1983. In the interim of this letter, I met with Union Carbide in Durham, North Carolina. I believe the letters themselves are self-explanatory.

We are now in correspondence with various companies requesting prices and time to do this work that is required. The answer to this inquiry will have a big bearing on our decision to arbitrate this matter with Union Carbide.

Each year we have to report to the government our paundage and dollar value of the two products in question, so I have taken the liberty to enclose copies of the five year summary of that expert for your files.

this work. As soon as we get all the date, we feel like we can do all the work much cheaper then the Carbide figure. We will forward same to you upon receipt.

Cordially yours,

Clinton C. Shipman

President

CCS/bar

Enclosures

Commercial/financial information may be entitled to confidential treatment



UNION CARBIDE AGRICULTURAL PRODUCTS COMPANY, Inc.

P O BOX 12014, T. W ALEXANDER DRIVE RESEARCH TRIANGLE PARK, N C. 27709

1919:549-2000

March 4, 1983

CERTIFIED MAIL No. P 353 488 252

Mr. Clinton C. Shipman, President Greenwood Chemical Company P. O. Box 26 Greenwood, VA 22943

Dear Mr. Shipman:

Re: Data Compensation for Naphthaleneacetic Acid (NAA) and Naphthaleneacetic Acid Sodium Salt (Sodium NAA)

Based upon our February 25, 1983 meeting, we re-evaluated our compensation claim for Naphthaleneacetic acid and sodium salt. We deleted the compensation request for the acute oral, dermal, eye, inhalation, and dermal sensitization studies for NAA, as well as the acute oral, dermal, eye, and inhalation studies for sodium NAA, since Greenwood Chemical Company stated they will develop their own data to fill those gaps identified in the June 1982 Registration Standard.

Additionally, we deleted our claim for compensation for Naphthaleneacetamide, since Greenwood stated they do not hold a registration for this active ingredient, nor do they plan to apply for a new registration without first filing an offer to pay to Union Carbide Agricultural Products Company, Inc.

Unless we reach agreement as to the amount payable to Union Carbide Agricultural Products Company, Inc., we would be forced to promptly request binding arbitration pursuant to the Federal Insecticide, Fungicide and Rodenticide Act.

Mr. Clinton C. Shipman, President March 4, 1983 Page 2

Please be aware that the identified cost does not take into account the time value of money, risks in developing the data, skilled time of personnel administering program, and our corporate overhead. Our claim under binding arbitration would be significantly greater than the requested compensation stated in this correspondence.

We would appreciate a prompt resolution of this request.

Sincerely

Warren A. Davi's

Registration Manager Herbicides/Growth Regulators

WAD:db

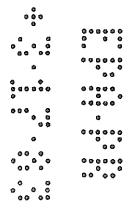
cc: R. Freeman

P. Suhr

R. deWilde

R. J. Otten

D. Page



Data Compensation Claim for Naphthaleneacetic Acid and Sodium Salt

| | Compensable Data 1970 thru June 1982 | New Data Required 1982 thru 1984 | Totals |
|--|---|--------------------------------------|---|
| NAA Na Salt | \$ 370,370 \$ 7,940 \$ 378,310 | \$ 62,000 \$ 75,000 \$ 137,000 | \$ 432,370 \$ 82,940 \$ 515,310 |
| 163.82-1 163.83-3 163.84-2,3,4 Residue 163.71-1 thru 163.72-3 | \$ 300,000 35,000 19,700 8,200 | \$ 50,000 75,000 | \$ 300,000 85,000 19,700 75,000 8,200 |
| | \$ 362,900 | \$ 125,000 | \$ 487,900 |
| 163.81-1 thru 163.81-5 | \$ 15,410 | \$ 12,000 | \$ <u>27,410</u> |
| Total Data Cost | \$ 378,310 | \$ 137,000 | \$ 515,310 |

Greenwood Chemical Company's Share for Data Development (calculated as ½ total cost)

| Compensable Data 1970 thru June 1982 | New Data Required 1982 thru 1985 | Total |
|---|-------------------------------------|------------|
| \$ 189,155 | \$ 68,500 | \$ 257,655 |

NOTES:

- (1) These figures do not include the acute toxicology for Naphthaleneacetic acid sodium salt (\$7,940) and Naphthaleneacetic acid (\$14,470) that has been filed by Union Carbide Agricultural Products Company, Inc. Greenwood trassitated they would independently develop these data at their own expense. """

 Failure to develop the studies, submit the reports, and receive EPA wallidation of the work as satisfying EPA guidelines would require Greenwood to rely on our data and pay subsequent compensation.
- (2) Data cost for Naphthaleneacetic acid acetamide (\$104,325) were not calculated into our claim since Greenwood has stated they do not have, nor do they plan to receive, registration for the amide. Should Greenwood elect to register the amide, compensation for $\frac{1}{2}$ of the then current data base (including planned work requested by EPA) would be required.



UNION CARBIDE AGRICULTURAL PRODUCTS COMPANY, Inc.

P. O. SOX 12014. T. W. ALEXANDER DRIVE RESEARCH TRIANGLE PARK, N. C. 27709

(919) 549-2000

January 7, 1983

CERTIFIED MAIL NO. P 353 488 244

Mr. Clinton C. Shipman President Greenwood Chemical Company P. O. Box 26 Greenwood, VA 22943

Dear Mr. Shipman:

Re: Compensation for Naphthaleneacetic Acid, Sodium Salt and Acetamide Data

Based upon your December 6, 1982, offer to share in the cost of NAA data we would welcome the opportunity to meet with Greenwood. Prior to an actual meeting, we would appreciate receiving an itemized list of those studies Greenwood has in progress that will fill identified gaps in the registration standard.

Also, We would like to emphasize that compensable data for NAA is based upon:

- Data gaps identified by EPA for NAA
- 2. Existing current data base cited and used by EPA in developing the registration standard

To permit you to prepare for our meeting we are appending a detailed . description of the data and cost of studies Union Carbide Agricultural. . Products Company, Inc. believe are compensable. We would appreciate prempt receipt of a similiar list from Greenwood identifying the nature and cost of studies you have in progress.

Sincerely,

Warren A. Davis

Registration Manager

Herbicides/Growth Regulators

WAD: db

0000000



Maphthaleneacetic Acid Technical

| SN | Cuideline Number | Description | Product | Conducted By | Reported Date | Oate Due | Total Costs | Est. Repl. Costs | Submission Date |
|-------------|----------------------------------|-------------------------------------|-------------------------------------|-------------------------|------------------|-------------|----------------|------------------------|----------------------|
| 8. | 163.81-1 | Acute Oral LD50-Rats | Naphthaleneacetic acld technical | Phe rmakon | 4-29-82 | | 1,675 | 1,675 | 5-20-82 |
| 11. | 163.81-2 | Acute Dermai LD50-Rabbits | Naphthaleneactic acid technical | Pha rmakon | 5-11-82 | | 875 | 875 | 5-20-82 |
| 17. | 163.81-3 | Acute Inhalation LC50-Rats | Naphthaleneacetic acid technical | MBR | 8-25-75 | | 195 | 3,700 | 2-10-82 |
| 20. | 163.81-4 | Primary Eye Irritation | Naphthaleneacetic acid technical | BRRC/UCC | 4-27-82 | | 640 | 640 | 5-20-82 |
| 25. | 163.81-5 | Primary Skin Irritation | Naphthaleneacetic acid technical | BRRC/UCC | 4-27-82 | | 580 | 580 | 5-20-82 |
| 26. | 163.81-6 | Dermal Sensitization Guinea Pigs | Naphthaleneactic acid technical | BRRC/UCC | 10-14-82 | | 7,000 | 7,000 | study in progress |
| 29. | 163.81-6 | Dermal Sensitization | Naphthaleneacetic | BRRC/UCC | | 6-83 | 5,000(1) | 5,000 | study in progress |
| <u>₃30.</u> | 163.82-1 | 90-Day Toxicity-Rats | Naphthaleneactic acid technical | CDC Research | 3-10-79 | | 29,110 | 100,000 | 7-19-79 |
| 31. | 163.82-1 | 6-Month Oral Toxicity-Dogs | Naphthaleneactic acid technical | CLARS | 8-1-79 | | 67,000 | 200,000 | 10-9-79 |
| 32. | 163.83-3 | Teratology Study-Rat | Naphthaleneacetic acid technical | Hunt Ingdon Research | 1-17-77 | | 7,400 | 35,000 | 7-17-79 |
| 33. | 163.63-3 | Teratology Study-Rabbit* | Naphthaleneacetic acid technical | BRRC/UCC | | 12-63 | 50,000(1) | 50,000 | study in progress |
| 34. | 163.84-2 163.84-3 163.84-4 | Ames Salmonella/ Microsome Plate | Naphthaleneacetic acid technical | Pharmak on | 5-26-78 | | 675 | 675 | 7-17-79 |
| 35. | 163.84-2 163.84-3 163.84-4 | Yeast Mitotic Crossing Over | Naphthaleneacetic acid technical | Pha rmakon | 7-17-78 | | 500 | 725 | 7-17-79 |

"This second species teratology study was specifically requested by EPA in the Registration Standard.



Naphthaleneacetic Acid Technical

| SN | Cuide line Number | Description | Product | Conducted By | Reported Date | Date Due | Total Costs | Est. Repl. Costs | Submission Date |
|-----|----------------------------------|--|-------------------------------------|-------------------|------------------|-------------|----------------|------------------------|--------------------|
| 36. | 163.84-2 163.84-3 163.84-4 | Yeast Reverse Mutation Assay | Naphthaleneacetic acid technical | Pha rmakon | 7-17-78 | | 500 | 500 | 7-17-79 |
| 37. | 163.84-2 163.84-3 163.84-4 | Yeast Mitotic Gene Conversion | Naphthaleneacetic acid technical | Pha rma kon | 7-17-78 | | 500 | 500 | 7-17-79 |
| 38. | 163.84-2 163.84-3 163.84-4 | E-Coli DNA polymerase (Deficient Assay | Naphthaleneacetic acid technical | Pha rma kon | 7-25-78 | | 775 | 800 | 7-17-79 |
| 39. | 163.84-2 163.84-3 163.84-4 | Micronucleus Test | Naphthaleneacetic acid technical | Pharmakon | 1-30-79 | * | 1,475 | 1,500 | 7-17-79 |
| 40. | 163.84-2 163.84-3 163.84-4 | Dominant Lethal Study | Naphthaleneacetic acid technical | Pha rma kon | 2-28-79 | | 14,000 | 15,000 | 7-17-79 |
| MI. | 163.71-1 | Acute Oral LD50-Mallard Duck | Naphthaleneacetic acid tachnical | Truslow Farms | 5-27-76 | | 1,429 | 1,900 | 7-17-79 |
| 42. | 163.71-1 | Acute Oral LD50-BobWhite Quail | Naphthaleneacetic acid technical | Wildlife Intl. | 5-30-79 | | 1,225 | 1,700 | 7-17-79 |
| 46. | 163.71-2 | Eight Day Dietary LC50 Mallard Duck | Naphthaleneacetic acid technical | Truslow Farms | 5-27-76 | | 1,429 | 1,600 | 7-17-79 |
| 47. | 163.71-2 | Eight Day Dietary LC50 Bobwhite Quali | Naphthaleneacetic acid technical | Trustow Farms | 5-27-76 | | 1,250 | 1,400 | 7-17-79 |
| 49. | 163.72-1 | Acute Toxicity LC50 Freshwater Fish Rainbow Trout & Bluegill | Naphthaleneacetic acid technical | EG&G Bionomics | 4-81 | | 600 | 800 | 10-5-81 |
| 51. | 163.72-3 | Acute Toxicity LC50 Water Flee Daphnia | Naphthaleneacetic acid technical | EG&G Bionomics | 4-81 | | 600 | 800 | 10-5-81 |
| | | | | | to | to is | 194,433 | 432,370 | |







Sodium Salt NAA Technical

| SN | Cuideline Number | Description | Product | Conducted By | Reported Date | Date Due | Total Costs | Est. Repl. Costs | Submission Date |
|-----|---------------------|------------------------------|------------------------------|-----------------|------------------|-------------|----------------|------------------------|--------------------|
| 7, | 163.81-1 | Acute Oral LD50-Rats | Sodium Salt NAA technical | BRRC/UCC | 5-27-82 | | 1,760 | 1,800 | 5-20-82 |
| 14. | 163.81-2 | Acute Dermal LD50-Rabbits | Sodium Salt NAA | BRRC/UCC | 5 - 27-82 | | 5,000 | 5,000 | 5-20-82 |
| 21. | 163.81-4. | Primary Eye Irritation | Sodium Salt NAA technical | BRRC/UCC | 5-27-82 | | 640 | 640 | 5-20-82 |
| 27. | 163.81-5 | Primary Skin Irritation | Sodium Salt NAA technical | BRRC/UCC | 5-27-82 | | 500 | 500 | 5-20-82 |
| 54. | Residue | Residue Data-Apples | NAA-800 Salt | ncc | | 12-82 | 9,046 | 10,000 | pend I ng |
| | | Residue Data-Pears | NAA-800 Salt | ncc | | 12-82 | 9,046 | 10,000 | pend i ng |
| | | Method of Analysis Olives | NAA and Derivatives | UCC | 3-82 | | 18,092 | 18,333 | |
| | | Method of Analysis Apples | NAA and Derivatives | UCC | 3-82 | | 18,092 | 18,333 | |
| | | Method of Analysis Pears | NAA and Derivatives | ucc | 3-82 | | 18,092 | 18,333 | |
| | | | | | | | 80,268 | 82,939 | |

These data were specifically requested in the Registration Standard for NAA.



Page 3

1226y revised from 1042y/13y 21-7-83







Naphthalene Acetamide Technical

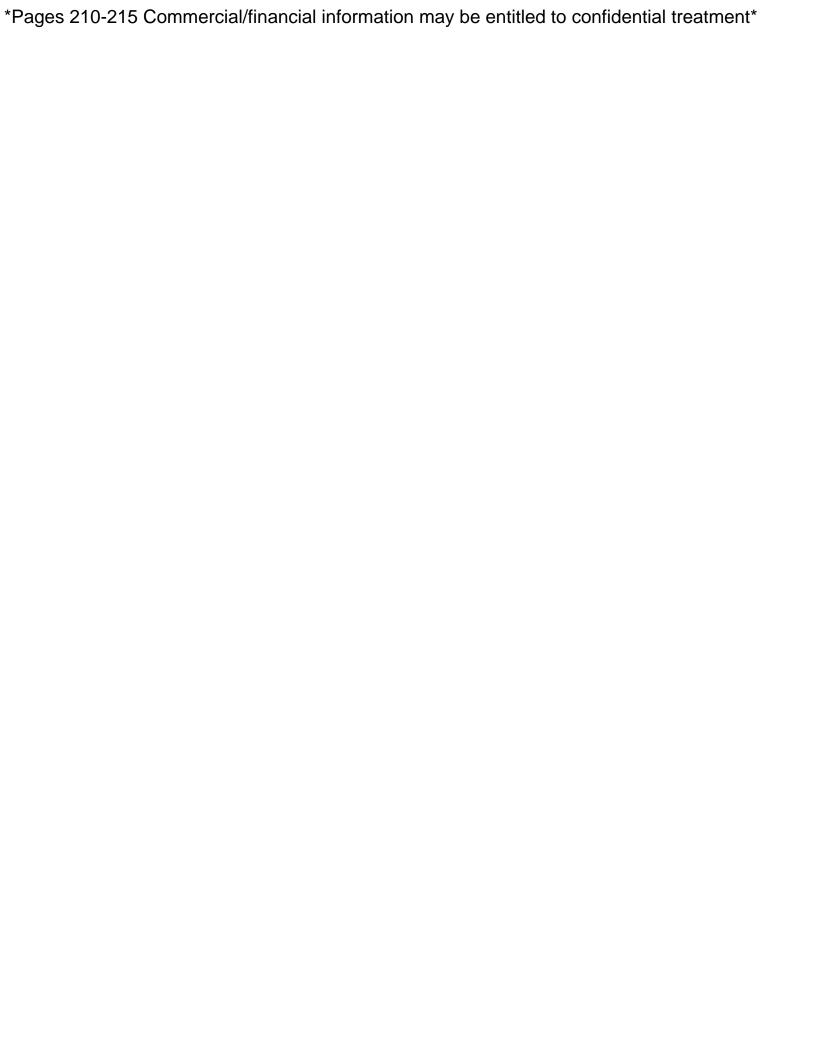
| SN | Guideline Number | Description | Product | Conducted By | Reported Date | Da te Due | Total Costs | Est. Repl. Costs | Submission Date |
|-----|---------------------|-------------------------------|---------------------------------------|--------------------|------------------|--------------|----------------|------------------------|--------------------|
| 9. | 163.81-1 | Acute Oral LD50-Rats | Naphthalene acetamide technical | Pha rma kon | 4-26-82 | | 1.675 | 1,675 | 5-20-82 |
| 12. | 163.81~2 | Acute Dermal LD50-Rabbits | Naphthalena acetamide technical | Pha rma kon | 5-11-82 | | 875 | 875 | 5-20-82 |
| 16. | 163.81-3 | Acute Inhalation LC50-Rats | Naphthalene acetamide technical | MBR | 6-25-75 | | 195 | 3,700 | 2-10-82 |
| 22. | 163.81-4 | Primary Eye Irritation | Naphthaleno acetamide technical | Pha risa kon | 5-11-82 | | 575 | 575 | 5-20-82 • |
| 24. | 163.81-5 | Primary Skin Irritation | Naphthalene acetamide technical | BRRC/UCC | 4-20-82 | | 500 | 500 | 5-20-82 |
| 52. | 163, 161-1 | Hydrolysis ^a | Naphthalene acetamide technicai | UCC | | 10-82 | 21,847 | 22,000 | pend i ng |
| | | | | | | | 25,667 | 29,325 | |
| 55. | Metabolism | Plant Metabolism ^b | Naphthalene acetamide technical | UCC/or contract | | | 75,000 | 75,000 | pend i ng |
| | | | | | | | 100.667 | 104,325 | |

The hydrolysis study was specifically requested by EPA in the registration standard for NAA. Based upon preliminary indications from the Hydrolysis data it is quite likely EPA will require a plant metabolism study.



Page 4

1226y revised from 1042y/13y : 1-7-83



Clinton B. Shipman Greenwood Chemical Comapny stata Highway 690 P.O. Box 26 Greenwood, VA 22943

MR 22 193

Dear Mr. Shipman:

Subject: MAA Reregistration

1-Haphthalene Acetic Acid, Sodium Salt

EPA Registration No. 11546-1 1-Waphtbalene Acetic Acid EPA Registration No. 11546-2/

Your Submissions of January 17, January 31,

and Pebruary 16, 1983

We have completed our review of the Acute Dermal Toxicity Study, Primary Bye Irritation Study and Primary Skin Irritation Study. These studies are acceptable and fulfill the requirements for such studies in the NAA meregistration Standard.

Labeling comments are reserved until we have received and reviewed the required Acute Oral, Acute Inhalation and Dermal Sensitization studies.

For your future reference the following EPA Accession Numbers have been assigned to the data submitted.

| | pata | | * \$ | EPA Accession No. |
|----|----------------|-----------------|--|-------------------|
| | h v jetak | | | |
| Ac | ute Dermal To: | ricity Study | | 249481 |
| PC | imary Dermal | rritation Study | | 249319 |
| Pr | imary Bye Ire: | ltation Study | en e | 249320 |

Sincerely yours,

Robert J. Taylor Product Manager (25) MR Pungicide-Herbicide Branch Registration Division (TS-767C)

RD:REMMERS:DCR-25315:WANG-3176C:mbd:Raven:479-2013:3/18/83

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1, REGISTRATION NUMBER CYCLE 2. DATE RECEIVED SUBMISSION REVIEW RECORD DAY 2 6 20 83 01 G 3. JCID PUBLICATION NECESSARY 4. PETITION NO. RECEIVED PM TEAM MÓ DAY □ №0 YES ٦ 8 01 7. PRODUCT MANAGER 6. METHOD OF SUPPORT NO. 8. PROJECTED RETURN MO DAY □ 2c _____ 2@ 9. DATE PULLED 10. DATE PUBLISHED 11. ACTION TYPE CODE 12, OUTGOING DATE Primary eye - Primary Stin YR DAY 5 DATE REVIEW COMPLETE! REV SEQ. REVIEW TYPE REVIEWER COM-SIGNATURE OF REVIEWER REVIEW TYPE CODE MENT (Initials) MÓ ΥR REVIEWABILITY TEAM PRODUCT MANAGER TEAM EFFICAGY REVIEW 8 PRODUCT MANAGER TEAM HUMAN SAPETY REVIEW PRODUCT MANAGER TEAMEN-VIRONMENTAL SAPETY REVIEW D PRODUCT MANAGER TEAM RESUMMISSION REVIEW Ē PRODUCT MANAGER G INTERAGENCY REFERRAL H COST-BENEPIT REVIEW PUBLIC COMMENTS REVIEW EEE BRANCH INSECTICIDE EFFICACY REE BRANCH HERBICIDE EFFICACY K ERE BRANCH FUNGICIDE EFFICACY EEE BRANCH ROBENTICIDE EFFICACY M EEE BRANCH DISINFECTANT EFFICACY N CHEMISTRY BRANCH RESIDUE CHEMISTRY 0 EEE BRANCH ENVIRON . MENTAL CHEMISTRY Q Ø TOXICOLOGY BRANCH HUMAN SAFETY Q EEE BRANCH ENVIRON-MENTAL SAPETY S RL-013 Type of Response PRODUCT MANAGER SIGNATURE CODE

EPA Form 8570-13 (3-75)

217

| Subject : | EPA Registration Number: 11546-2 |
|--|--|
| | IPA Registration Neember: 11546-2 |
| From: | Deland J. Grekam JHB/181 E 3/10/23 |
| | |
| - D | Robert Daylor Presduct Manager (25) |
| | applicant: Greenwood Chemical Company P.O. Box 26 |
| | Therwood 2/A 22943 |
| | active Ingredient: 10 Naph thalene active acid. 98.5% Inert Ingredients. 1.5% |
| Processor (1997) - 1 - Part Mad State Printers and A Transmiss | elnest Inquedients 1.5% |
| | Bookground: Submitted acute Dermal, Eye Instation and Shir Instation Suchies in |
| | Compliance with the Paphthalene Dieti acid Registration Standard to fulfill data gaps. Data under accession minuters: 249 481, 249 320, 249 319. Method appears not indicated Studies conducted by Bissey Leptons Experietion. |
| and a finished the second of t | Data under accession minutes: 249 481, 249 320, 249 319. Method gauppart not indicated |
| | Studies conducted by Bisary Systems Constitution. |
| | Becommendations. (D. HB / IS funds these studies acceptable to support conditional negistration of this product. |
| The state of the s | and the second s |
| memoral years and a second | Dermal Sensitivation studies were not submitted and here studies must be submitted |
| - September of the sept | and here studies must be submitted |
| andige defect of materials and a supplied to the second second second second second second second second second | A CONTRACTOR OF A CONTRACTOR O |

Jabel: Debeling comments reserved ountil presuously mentioned data has been submitted and for cited. (1) Create Dermal Doviety Study Bioasay Systems Corp.; Regist # 11480; Jan. 24, 1983; EPA accession 24, 24948/. Proodure: Five make and five female rabbits received 29 1kg of the test-material at abraded skin setes under occlusiere arap par 24 hour exposure, Observations made frequently on Hoday. Peciopsy performed on all animals. Besilte No mortalities. Three-male orabbets spould wife is in the cage on the moining of day 3, few feces that offerwar and normal exceeder on day 4. No other signs of toxicity roled Ao abnormalitied at neargony. LD50 greater Than 29 lkg. Study Classification: Core Suiteline Date.

Dozel # 11480; January 10,1983; EPA acc. # 249320. Procedure: Mine rabbits received a 0.19 8, the test material in one eye each. He treated eys of three of the rabbilo were washed 20-30 Secondo apper treatment. Observations made at 24, 48 and 72 hours after twatment and at Good 7 days. On day 7, sesitation was present, thus obscriptions were species continued theorigh day group and 3/3 of the washed group had corneal spacity (5/6=30) (2/3=20); 3/6 + 13 iris irritation (3/6=5) (13=5), 1/6+3/3 Ryperemea (1/6=1, 2/6=2) (2/3=1, 13=2), chemesis (3/6=1, 1/6=2, 7/6=3) and chocharge (3/6=1, 3/6=2, 3/6=3) (1/3=1, 1/3=2, 1/3=3) Oct 7 days, We had corneal opacity (76=20, 76=40);
2/6 sis circlation (76=5) " The hyperemia (76=1);
2/6 chemosis (4/6=1) and 76 discharge (2/6=1).

Bliritation and opacity had cleared in 3/3 asimals of the washed group. at day 16, all opacity and writation in unwaster group had cleared. Skuly Classification: Core Suddine Dato. Thicity Cotegory! II-WARDING-(3) Primary Dermal britation Study. Bioarmy Systems Corp.; Broyet # 11480; Gan. 10, 1983, EPA Occ. # 249 310.

| | material of four abused and reconstruct skin |
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| And the second s | Low exposure. Observations use made at |
| | 25/ and 72 balls all days and |
| . marana (, , , , , , , , , , , , , , , , , , | 124 and 72 hours after treatment. |
| er and er en en er e | Regulto " At 24 hour 5/2 had alean (5/2) |
| | Resulta: Ot 24 hours, To had edema (5/6=1) and ND eightening present. at 22 hours, roedema present. Premary diretation Scare was |
| and security in the second security of the second security is a second s | many the Remark of the transferred |
| terresidado en | 0.38. |
| The second secon | The state of the s |
| and the state of t | Study Classification: Core Suddeline Data |
| | |
| | Topicity Category: IT - CAUTTON. |
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State Highway 690 P. O. Box 26 Greenwood, Virginia 22943

Telephone 703 456-6832

Acc# 29320

249319

January 17, 1983

Robert J. Taylor
Product Manager (25)
Registration Division (TS767C)
ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Dear Mr. Paylor:

Subject: 1-Naphthalene Acetic Acid, Sodium Salt

EPA Registration No. 11546-1 1-Naphthalene Acetic Acid EPA Registration No. 11546-2

We are enclosing copies of the results of testing completed by Bioassay for 163.81-4, Primary Eye Irritation and 163.81-5, Primary Skin Trritation. We will submit these test results as we receive them, which are required.

We are enclosing a copy of a letter we received from Union Carbide in response to the letters we had written to them concerning sharing the cost of the data collected thus far. Their letter is self explanatory. We will study their proposals, and answer and meet with them at the earliest possible date.

If there are any questions concerning this information, please contact either Nrs. Jane Goodband with Bioassay or myself.

Cordially yours,

Clinton C. Shipman

President

CCS/bar

Enclosures: Letter from Union Carbide
Test Results: Primary Eye Irritation
Primary Dermal Irritation

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222



UNION CARBIDE AGRICULTURAL PRODUCTS COMPANY. Inc.

P O GOX 12014 T W ALEXANDER OF P RESEARCH FRANCH E PARK WELL FOR THE

18-9-189-1000

January 7, 1983

CERTIFIED MAIL NO. P 353 488 244

Mr. Clinton C. Shipman President Greenwood Chemical Company P. D. Box 26 Greenwood, VA 22943

Dear Mr. Shipman:

Re: Compensation for Naphthaleneacetic Acid, Sodium Salt and Acetamide Data

Based upon your December 6. 1982, offer to share in the cost of NAA data we would welcome the opportunity to meet with Greenwood. Prior to an actual meeting, we would appreciate receiving an itemized list of those studies Greenwood has in progress that will fill identified gaps in the registration standard.

Also, We would like to emphasize that compensable data for NAA is based upon:

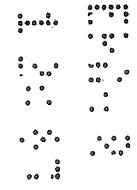
- Data gaps identified by EPA for NAA
- 2. Existing current data base cited and used by EPA in developing the registration standard

To permit you to prepare for our meeting we are appending a detailed description of the data and cost of studies Union Carbide Agricultural Products Company. Inc. believe and the well appreciate prompt receipt of a simpliar list from Greenwood, identifying the nature and cost of studies you have in progress.

Sincerely,

Warren A. Davis Registration Manager Herbicides/Growth Regulators

WAD: db



NAA DATA COMPENSATION Naphthaleneacetic Acid Technical

Fat. Guideline Conducted Reported Date Total Rept. Submission Number Description Product SM Ву Date Dire Costs Costs Date 163.81-1 Acute Oral LD50-Rats Naphthaleneacetic Pharmakon 4-29-82 8. 1,675 1,675 5-20-82 acid technical 11. 163.81-2 Acute Dermai LD50-Rabbit-Naphthaleneactic Pharmakon 875 5-11-82 875 5-20-82 acid technical 17. 163.81-3 Acute Inhalation LC50-Rate Naphthaleneacetic MBR 8-25-75 195 3,700 5-10-95 acid technical 20. 163.81-4 Primary Tye irritation Naphthaleneacetic BRRC/UCC 4-27-82 640 640 5-20-82 acid Lechnical 163.81-5 Primary Skin (rritation Maphthaleneacetic BRRC/UCC 4-27-62 580 580 5-20-82 acid technical 26. 163.81-6 Dermal Sensitization Nachthaleneactic BRRC/UCC 10-14-82 7.000 7.000 study in Guinea Pigs acid technical progress Naphtha leneacetic BRRC/UCC 5-83 163.81-6 Dermal Sensitization 5.000(1) 5.000 study in acid technical progress Naphthaleneactic CDC 163.82-1 90-Day loxicity-Rats 3-10-79 29,110 100,000 7-19-79 30. acid technical Research 163.82-1 6-Month Oral Toxicity-Dogs Naphthaleneactic ELARS 8-1-79 67,000 200,000 10-9-79 31. acid technical Naphtha leneacetic Hunt i ngdon 1-17-17 7,400 32. 163.83-3 Teratology Study-Rat 35,000 7-17-79 acid technical Research Naphthaleneacetic ' BRRC/UCC 50,000(1) 33. 163.83-3 Teratology Study-Rabbit* 12-83 50,000 study in acid technical progress Naphtha leneacetic 675 675 163.64-2 Pharmakon 5-26-78 Ames Salmonella/ 7-17-79 acid technical 163.84-3 Microsome Plate 163.84-4 500 725 35. 163.84-2 Yeast Mitotic Crossing Over Naphthaleneacetic Pharmakon 7-17-78 7-17-79 163.64-3 acid technical

"This second species teratology study was specifically requested by EPA in the Registration Standard. (1) These costs are estimated.

Page 1

1226y revised from 1042y/13y 1-7-83

163.84-4







NAA DATA COMPENSATION

Naphthaleneacetic Acid Technical

| SN | Guideline Number | Description | Product | Conducted By | Reported Date | Date Due | Total Costs | Est. Ropi. Costs | Submission Date |
|------------|----------------------------------|--|--------------------------------------|-------------------|------------------|-------------|----------------|------------------------|--------------------|
| 36. | S-48.231 E-48.231 4-48.231 | Yeast Reverse Mutation Astay | Naphthaleneacetic acid technical | Plia raakon | 7-17-78 | | 500 | 500 | 7-17-79 |
| 37. | 163.84-2 163.84-3 163.84-4 | Yeast Mitotic Gene Conversion | Maphthaleneacetic acid technical | Pharmakon | 7-17-78 | | 500 | 500 | 7-17-79 |
| 38. | 163.84-2 163.84-3 163.84-4 | E-Coli DNA polymerase I Deficient Assay | Naphtha beneacetic acid technical | Pha rmakon | 7-25-78 | | 775 | 800 | 7-17-79 |
| 39. | 163.84-2 163.84-3 163.84-4 | Micronucleus lest | Naphthaleneacetic acid technical | Pha rma kon | 1-30-79 | | 1.475 | 1,500 | 7-17-79 |
| 40. | 163.84-2 163.84-3 163.84-4 | Dominant Lothal Study | Naphthalenescetic scid_technical | Pharmakon | 2-28-79 | | 14,000 | 15,000 | 7-17-79 |
| bı. | 163.71-1 | Acute Oral LD50-Mallard Do k | Naphthaleneacetic acid technical | Truslow Farms | 5-27-76 | | 1,429 | 1,900 | 7-17-79 |
| 42. | 163.71-1 | Acute Oral LD50-Bobwhite Quall | Naphthaleneacetic acid technical | Wildlife Intl. | 5-30-79 | | 1,225 | 1,700 | 7-17-79 |
| 46. | 163.71-2 | Eight Day Dietary LC50 Mallard Duck | Naphthaleneacctic acid technical | Truslow farms | 5-27-76 | | 1,429 | 1,600 | 7-17-79 |
| 47. | 163.71-2 | Eight Day Dietary LC50 Bobwhite Quail | Naphthaleneacetic acid technical | irusiov faras | 5-27-76 | | 1,250 | 1,400 | 7-17-79 |
| ц9. | 163.72-1 | Acute Toxicity LC50 Freshwater Fish Rainbow Trout & Bluegill | Naphthaleneacetic acid technical | tG&G Bionomics | 4-81 | | 600 | 800 | 10-5-81 |
| 51. | 163.72-3 | Acute Toxicity LC50 Water flea Daphnia | Naphtheleneacetic acid technical | EC&G Bionomics | 4-81 | | 600 | 800 | 10-5-81 |
| | | | | | to | tals | 194.433 | 432,370 | |





NAM DATA COMPENSATION Sodium Selt NAM Technical

| SM | Guideline Kuaber | Description | Product | Conducted By | Reported Date | Data Due | Total Costs | Est. Repi. Costs | Submission Date |
|-----|------------------------|------------------------------|------------------------------|-----------------|------------------|-------------|----------------|------------------------|--------------------|
| 7. | 163.81-1 | Acuto Oral 1050-Rats | Sodium Salt NAA technical | BRRC/UCC | 5-27-82 | | 1,760 | 1,800 | 5-20-82 |
| 16. | 163.81-2 | Acute Dormal LD50-Rabbits | Sodium Salt NAA | BRRC/UCC | 5-27-82 | | 5,000 | 5,000 | 5-20-82 |
| 21. | 163.81=4 | Primary Eye Irritation | Sodium Salt NAA technical | BRRC/UCC | 5-27-82 | | 640 | 640 | 5-20-82 |
| 27. | 163.81-5 | Primary Skin Irritation | Sodium Salt NAA technical | BRRC/UCC | 5-27-62 | | 500 | 500 | 5-20-82 |
| 54. | Ros i due ^e | Residue Data-Apples | NAA-800 Salt | VCC | | 12-82 | 9,046 | 10,000 | pend ing |
| | | Residue Data-Pears | NAA-800 Salt | UCC | | 12-82 | 9,046 | 10.000 | pending |
| | | Nethud of Analysis Olives | NAA and Derivatives | ucc | 3-62 | | 18,092 | 18,333 | |
| | | Method of Analysis Apples | NAA and Derivatives | vcc | 3-62 | | 18,092 | 18,333 | |
| | | Method of Analysis Pears | NAA and Derivativos | ncc | 3-62 | | 18,092 | 18,333 | |
| | | | | | • | | 80,268 | 82,939 | |

*These data were specifically requested in the Registration Standard for NAA.





NAA DATA COMPENSATION

Naphthalene Acetamide Technical

| sn —— | Guideline Number | Description | Product | Conducted By | Reported Dete | Date Due | Total Costs | Est. Repl. Costs | Submission Date |
|----------|---------------------|----------------------------|---|--------------------|------------------|-------------|-------------------|------------------------|--------------------|
| 9. | 163.81-1 | Acute Orel LD50-Rats | Raphtha lene acetamide technica l | Pharmakon | 4-26-82 | | 1,675 | 1,675 | 5-20-82 |
| 12. | 163.81-2 | Acute Dermal LD50-Rabbits | Naphthalene acetamide technical | Pharmakon . | 5-11-82 | | 875 | 875 | 5-20-82 |
| 18. | 163.81-3 | Acute Inhalation LC50-Rats | Naphtha lene acetamide technica I | MBR | 8-25-75 | | 195 | 3,700 | 2-10-82 |
| 22. | 163.81-4 | Primary Fye Irritation | Naphthaiene acetamide technicai | Pharmakon | 5-11-82 | | 575 | 575 | 5-20-62 |
| 24, | 163.81-5 | Primary Skin Irritation | Naphthalenc acetamide technical | BRRC/UCC | 4-20-82 | | 500 | 500 | 5-20-82 |
| 52. | 163.161-1 | Hydrolysis# · | Naphtha Ione acetamide technica I | UĆC | | 10-62 | 21,847 | 22,000 | pend i ng |
| | | | | | | | 25,667 | 29,325 | |
| 55. | Metabolism | Plant Metabolisme | Naphthalene acetamide technical | UCC/or contract | | | 75,000 | 75,000 | pend i ng |
| | | | | | | | 100,667 | 104,325 | |

^{*} The hydrolysis study was specifically requested by EPA in the registration standard for MAA. Based upon preliminary indications from the Hydrolysis data it is quite likely EPA will require a plant metabolism study.

Bioassay Systems Corporation

225 Wildwood Avenue Woburn, Massachusetts 01801 617-933-9229

February 9, 1983

Mr. Clint Shipman
President
Greenwood Chemical Company
State Highway 690
P. O. Box 26
Greenwood, VA 22943

Dear Mr. Shipman:

9

Upon reviewing reports that I have already sent to you, I noticed a typo in the Primary Dermal Irritation Test. The accompanying Amendment to the Report should be kept with your final report and submitted to the agency with whom you are presently dealing.

Sincerely,

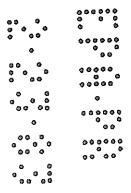
BIOASSAY SYSTEMS CORPORATION

Jane Coodbard

Jane B. Goodband Study Director

JBG:ec

enclosure



BIOASSAY SYSTEMS CORPORATION

Amendment to the Report for

Greenwood Chemical Co.

Bioassay Systems Project Number 11480

TEST: Primary Dermal Irritation Test

CHANGE: On the Primary Dermal Irritation data record sheet, Rabbit #7026 should have a score of 0/1 at 24 hours at Abraded Test Site 1.

SIGNATURES:

Study Director: Jane B. Googbard 2/9/83

Quality Assurance Officer: Teles Mine 3/4/6

State Highway 590
P. C. Box 26
Greenwood, Virginia 2294:

Telephone 703 456-6832

February 16, 1983

Robert J. Taylor Product Hansger (25) Registration Division (TS767C) ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.G. 20460

Dear Mr. Taylor:

Subject: 1-Naphthalene Acetic Acid Sodium Salt EPA Registration No. 11546-1 1-Naphthalene Acetic Acid EPA Registration No. 11546-2

EPA Accession No. 249461

Please find enclosed an additional copy of the Acute Dermal ToxicityStudy Performed on 1-Naphthalene Acetic Acid as well as a copy of correspondence from Bioassay for correction of error in the Primary Dermal Irritation Test.

We will supply EPA with two copies of all future test data we receive. We are sorry for any inconvenience this oversight may have caused your department.

Further test results will follow within the next two weeks as indicated by Bioassay. We will submit this data to you as soon as we receive it.

Cordially yours,

Bothaman Lobert

B. Shannon Roberts

BSR/ar

Enclosures: 2



Treenwood Chemical Company

MP THE BOX State Highway 690
P. O. Box 28
Greenwood, Virginia 22943

Telephone 703 456-6832

February 22, 1983

Robert J. Taylor Product Manager (25) Registration Division (TS767C) ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Dear Mr. Taylor:

Please find enclosed correspondence from Bioassay Systems Corporation concerning the results of the Acute Inhalation Toxicity study. Due to circumstances beyond our control or Bioassay's the final test results will not be submitted to us until mid-late April.

Upon receipt of this data, we will forward two copies to your office. We will forward any related correspondence and test data upon receipt.

If you have any questions or need additional information, please let us know.

Cordially yours,

B. Shannon Roberts

BSR/SF

Enclosures: 2 sets

70-100% of the rats continued to exhibit ocular discharge and dried red material on facial area and forepaws during post-exposure days 1-3 and 1 and 2, respectively.

Sporadic incidence of nasal and ocular discharges, yellow A-G staining, and dried red material on the facial area were evident on post-exposure observations days 3-14.

Postmortem (14 days post-exposure):

Most animals (8/10) exhibited pin point or raised multiple red or grey areas in the lungs. In 2/10 animals pale green or brown kidneys with dark red cortical/medullary borders were noted, and in lanimal a dialated pelvis was seen.

James B. Terrill, Ph.D Szudy Director

Feb 11,1983

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Bioassay Systems Corporation

225 Wildwood Avenue Woburn, Massachusetts 01801 617-933-9229 FEB 1 8 1983

February 16, 1983

Mr. Clint Shipman
President
Greenwood Chemical Company
P. O. Box 26
State Highway 690
Greenwood, VA 22943

Dear Mr. Shipman:

Enclosed is a preliminary draft report for the Acute Inhalation Toxicity Study of 1-Naphthalene Acetic Acid. The report shows that your sample caused no deaths to the rats during the exposure and 14 day observation period.

I have been informed that the final report will not be completed until mid-late April. Unfortunately, there is nothing I can do about it.

Please feel free to contact me if you have any questions.

Sincerely,

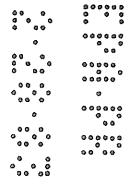
BIOASSAY SYSTEMS CORPORATION

Jan Goodbard

Jane B. Goodband Study Director

JBG:ec

enclosure



B-22 82-7621 SUMMARY DATA

AN ACUTE INHALATION TOXICITY STUDY OF 1-NAPTHALENE ACETIC ACID IN THE RAT

Test Facility: Bio/dynamics, Inc.

February 11, 1983

Mettlers Road

East Millstone, NJ 08873

Sponsor:

Bio Assay Systems 225 Wildwood Ave. Woburn, MA 01801

Attention:

Jane Goodband

Mgr. of Toxicology

Chamber Level:

Analytical Mean: 0.45 mg/l Nominal Delivery: 15 mg/l

Post-Exposure Environmental Conditions:

Temperature Range: 68 - 76°F Humidity Range: 42 - 84%

Mortality:

No mortality over 14 days.

Body Weights:

| | Exposure (g) | Termination (g) |
|---------|--------------|-----------------|
| Males | 297 | 362 |
| | 291 | 357 |
| | 285 | 350 |
| | 290 | 369 |
| | 290 | 381 |
| Females | 239 | 260 |
| | 245 | 263 |
| | 250 | 268 |
| | 235 | 242 |
| | 245 | 257 |

Major Signs:

In Chamber: Dried red material in the facial area was evident in 10-30% of the rats at the two-three- and four-hour intervals. 10-30% of the rats exhibited ocular discharge at the three-hour. $^{\circ}$ interval. $^{\circ}$ 10-30% of the rats exhibited irregular breathing at the three and four-hour intervals. $^{\circ}$ $^{\circ}$ $^{\circ}$

Post-Exposure: 70-100% of the rats exhibited ocular discharge and dried red material in the facial area at observation intervals 4 1/2 hours, 5 hours and 6 hours.

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70-100% of the rats continued to exhibit ocular discharge and dried red material on facial area and forepaws during postexposure days 1-3 and 1 and 2, respectively.

Sporadic incidence of masal and ocular discharges, yellow A-G staining, and dried red material on the facial area were evident on post-exposure observations days 3-14.

Postmortem (14 days post-exposure):

Most animals (8/10) exhibited pin point or raised multiple red or grey areas in the lungs. In 2/10 animals pale green or brown kidneys with dark red cortical/medullary borders were noted, and in 1 animal a dialated pelvis was seen.

Study Director

B. Serill Pl.D. 7. Ph.D. Feb 11,1983

00000 90000

Bioassay Systems Corporation

225 Wildwood Avenue Woburn, Massachusetts 01801 617-933-9229 FEB 1 8 1983

February 16, 1983

Mr. Clint Shipman
President
Greenwood Chemical Company
P. O. Box 26
State Highway 690
Greenwood, VA 22943

Dear Mr. Shipman:

Enclosed is a preliminary draft report for the Acute Inhalation Toxicity Study of 1-Naphthalene Acetic Acid. The report shows that your sample caused no deaths to the rats during the exposure and 14 day observation period.

I have been informed that the final report will not be completed until mid-late April. Unfortunately, there is nothing I can do about it.

Please feel free to contact me if you have any questions.

Sincerely,

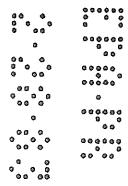
BIOASSAY SYSTEMS CORPORATION

Jan Goodbard

Jane B. Goodband Study Director

JBG:ec

enclosure



February 11, 1983

B-22 82-7621 SUMMARY DATA

AN ACUTE INHALATION TOXICITY STUDY OF 1-NAPTHALENE ACETIC ACID IN THE RAT

Test Facility: Bio/dynamics, Inc.

Mettlers Road

East Millstone, NJ 08873

Sponsor:

Bio Assay Systems 225 Wildwood Ave. Woburn, MA 01801

Attention:

Jane Goodband

Mgr. of Toxicology

Chamber Level:

Analytical Mean: 0.45 mg/l Nominal Delivery: 15 mg/l

Post-Exposure Environmental Conditions:

Temperature Range: 68 - 76°F Humidity Range: 42 - 84%

Mortality:

No mortality over 14 days.

Body Weights:

| | Exposure (g) | Termination (g) |
|---------|--------------|-----------------|
| Males | 297 | 362 |
| | 291 | 357 |
| | 285 | 350 |
| | 290 | 369 |
| | 290 | 381 |
| Females | 239 | 260 |
| | 245 | 263 |
| | 250 | 268 |
| | 235 | 242 |
| | 245 | 257 |

Major Signs:

In Chamber: Dried red material in the facial area was evident in 10-30% of the rats at the two-three- and four-hour intervals. 10-30% of the rats exhibited ocular discharge at the three-hour of the rats exhibited irregular breathing at the three and four-hour intervals. $^{\circ}$

Post-Exposure: 70-100% of the rats exhibited ocular discharge and dried red material in the facial area at observation intervals 4 1/2 hours, 5 hours and 6 hours.

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State Highway 690 P. O. Box 26 Greenwood, Virginia 2294:

Telephone 703 456-6832

December 20, 1982

Robert J. Taylor Product Manager 25 Registration Division (TS 767C) ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Dear Mr. Taylor:

We are enclosing a copy of a letter we received from Mrs. Jane Goodband with Bioassay Systems Corporation. The letter is self explanatory, but we did want to let you know that the required data is being taken care of, even thought there may be a delay in obtaining the results.

We will keep you informed of any further developments in the reregistration of our products.

Wishing you a Merry Christmas and a Happy New Year!

Cordially yours,

B. Shannon Roberts

Enclosure: 1

Bioassay Systems Corporation

225 Wildwood Avenue Woburn, Massachusetts 01601 617-933-9229

DEC 1 7 1982

December 14, 1982

Mr. Clint Shipman
President
Greenwood Chemical Company
State Highway 690
P. O. Box 26
Greenwood, VA 22943

Dear Mr. Shipman:

Due to circumstances beyond my control, the contract laboratory, Bio/dynamics, Inc., will be unable to initiate the Inhalation Toxicity Test in rats on your sample of 1-Napthalene Acetic Acid before January 21, 1983. You can expect a preliminary report by February 20, with the final report being submitted on or before March 30, 1983.

Bioassay Systems will be initiating the remainder of the tests the week of December 13, 1982 with final reports being submitted as soon as each test has been completed.

I apologize for the delay in any scheduling plans by Greenwood Chemical for submission to the EPA. Unfortunately, there is no other alternative.

Best wishes for the New Year to both you and Shannon.

Sincerely,

BIOASSAY SYSTEMS CORPORATION

Yane Goodbard

Jane B. Goodband Manager, Acute Toxicology Srvice

JBG:ec

December 6, 1982

Jane Goodband BIOASSAY SYSTEMS CORPORATION 225 Wildwood Avenue Woburn, MA 01801

Dear Jane:

We have received acceptance from EPA on the protocols that we submitted for 1-Naphthalene Acetic Acid. This is your authorization to start the test at your earliest convenience. A copy of the acceptance letter is enclosed.

A three pound sample of 1-Naphthalene Acetic Acid is being forwarded to you via UPS. Please advise by telephone if there is anything else you may need.

Cordially yours,

Clinton C. Shipman

1 mpm

President

CCS/bar

Enclosures: Letter - EPA

Product Manager (25)
Fungicide-Herbicide Branch
Registration Division
U.S. ENVIRONMENTAL PROTECTION AGENCY.
401 M Street, S.W.
Washington, D.C. 20460

December 6, 1982

Warren A. Davis
Registration Manager
Herbicide/Growth Regulators
UNION CARBIDE AGRICULTURAL PRODUCTS COMPANY, INC.
P.O. Box 12014
T.W. Alexander Drive
Research Triangle Park, N.C. 27709

Dear Mr. Davis:

We are in receipt of your letter by certify mail, no. P 353 488 238, dated November 30, 1982.

In answer to your letter, we, too, are in the process of developing and collecting the data called for by EPA. There is no way to stop some of this development work, therefore, we have already committed ourselves to having it done, so we are letting it stand.

Even though data is being collected, we still would like to enter into an agreement to pay compensation to Union Carbide Agricultural Products Company. I believe this fulfills the question you asked in the second point of your letter.

Waiting to hear from you concerning time, place, and personnel to set these negotiations in motion.

I remain,

Coridally yours,

President

CCS/bar

cc: Robert Taylor
Product Manager 25
Fungicide-Herbicide Branch
Registration Division (TS-7670)
401 M Street, S.W.
Washington, D.C. 20460

December 2, 1982

Mr. Robert J. Taylor Product Manager 25 Registration Division (TS767C) ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460 Subject: 1-Naphthalene Acetic Acid EPA Registration No.11546-1 1-Naphthalene Acetic Acid Sodium Salt EPA Registration No.11546-2

Dear Mr. Taylor:

We received your letter of November 29, 1982 today with the unsigned forms. Mr. Shipman has signed these and we are returning them to you to-day by certified mail.

On October 28, 1982 we sent your office copies of the protocols for the required toxicity data test. We have not heard from your office as to whether these are approved. We would appreciate your looking into this so that we can notify BioAssay to continue with the required testing as quickly as possible.

On October 7, 1982, we sent a letter to Union Carbide concerning obtaining the required data and working with them in obtaining this information. In a telephone conversation Mr. Shipman had with Mr. DeWilde we were informed we would receive a response within two weeks of October 26, 1982. To date we have not heard from Union Carbide, therefore, we have written to them again asking for a response, a copy of which is enclosed. We feel Union Carbide is not willing to cooperate with us, since they will not respond and have verbally threatened to put us out of the "Acid" business.

Mr. Shipman had a stroke on November 2, 1982 and has not been able to tend to the necessary matters at hand, therefore, anything EPA can do to expedite getting an answer to our protocols would be appreciated. We would also, appreciate anything you can do to lessen the worry and anxiety of the procedures for reregistration.

We will be looking forward to an early answer to our request about the protocols and hope to be able to complete reregistration of our Naphthalene Acetic Acid products.

Cordially yours,

Boshannon Robert

B. Shannon Roberts

ber

Enclosures: Letter - Union Carbide
Returned Attachments of 11/29/82

Stato Highway 690 P. O. Box 26 Greenwood, Virginia 22943

Telephone 703 456-6832

December 2, 1982

Mr. Robert J. Taylor Product Manager 25 Registration Division (TS-767C) ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Subject: 1-Naphthalene Acetic Acid EPA Registration No. 11546-2 1-Naphthalene Acetic Acid Sodium Salt EPA Registration No. 11546-1

Dear Mr. Taylor:

We received your letter of November 29, 1982 today with the unsigned forms. Mr. Shipman has signed these and we are returning them to reu today by cortified mail.

On October 28, 1982, we sent to your office copies of the protocols for the required toxicity data test. We have not heard from your office as to whether these are approved. We would appreciate your looking into this so that we can notify Biokesy to continue with the required testing as quickly as pessible.

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. Mr. Snipsen had a stroke on November 2, 1982, and has not been able ... to tend to the necessary matters at hand, therefore, we would appreciate, anything EPA can do to expedite getting an answer to our protocols. We would, also, appreciate anything you can do to lessen the worry and anxiety of the procedures for reregistration.

We will be looking forward to an early answer to our request about. the protocols and hope to be able to complete reregistration of our Nanhthelone Acetic Acid products.

Cordially yours.

3. Stanson Roberts

B. Shannon Roberts

ber

nclosures: Lottor - Union Carbide 🔸 -----Betuned Attachments of 11/29/82

December 2, 1982

Warren Davis, Head of Registration Group HILL CARBLE MURICULTURAL PRODUCTS, DRG. TWA Alexandra Drive P.O. Box 12014 Research Triangle Park, N.C. 27709

Dear Mr. Lavis:

We previously wrote to you on October 7, 1982 concerning the sharing of the cost of obtaining the data required for the EPA registration of 1-Waphthaless Acetic Acid products.

To date we have not received any response to our letter. Hr. Shipman discussed this matter with your Mr. Robert Devilde on October 26, 1982, and was informed we would receive a response within two weeks from the lawyers.

Jould you please check into this matter and let us know what remuneration Union Carbide would require if we were to share in this data. Your earliest reply would be appreciated.

We remain.

Cordially yours,

Mrs. B. Shannoz Roberts Treasurer

bor

cc: Kr. Robert Taylor, EPA Registration Ulvision

DATA COMPENSATION STATEMENT: PRESCRIPTION

| 24 834 0 30 0 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 | | |
|--|--|-----------------------|
| reduct Mane: 1-Naphthalene | Acetic Acid Sodium Salt & 1-Naphthalene Acetic | Acid |
| pplicant's Name & Address: | Greenwood Chemical Company | |
| Since State St | P.O. Box 26 | |
| ratio | Greenwood, VA 22943 | |
| ite of application for rere | gistratica: November 2, 1981 | |
| | 1-Naphthalene Acetic A | |
| ete Reregistration Standard | | |
| | Package Issued: August 18, 1981 | |
| In connection with appl | icant's application for reregistration under idance Package identified above: | ك |
| pplication, the approval wi (1) All the general tandard and Guidance Package valuation of the registrabi be product's composition an | nds and acknowledges that if EPA appowes the ll be based solely on EPA's consideration of secondary to the Registration of selections and the secondary to EPA applicant's product (taking into according to the uses its labe | 'A' s |
| all permit); and | No. of the second secon | |
| 191 191 | | |
| | scific data listed on the form entitled to which is part of this application. | 9 9 9 9 9 |
| Product-Specific Data Repor | | 96 6 |
| Product-Specific Data Repor (3) Applicant stat Urnished to the persons and | t" which is part of this application. es that offers to pay compensation have been | 96 9 |
| Product-Specific Data Repor (3) Applicant staturnished to the persons and dentified above. | to which is part of this application. es that offers to pay compensation have been in the form specified by the Guidance Packag | 96 9 |
| Product-Specific Data Reportation (3) Applicant state state state and state above. State October 28, 1982 | es that offers to pay compensation have been in the form specified by the Guidance Packer (signature) | 96 9 |
| (3) Applicant staternished to the persons and sentified above. October 28, 1982 Be of registrant's | to which is part of this application. es that offers to pay compensation have been in the form specified by the Guidance Packag | 96 9 |

STATULET OF WILLIAMS TO SEELS Diso an acazonat with other azgistravis for development of sata

anduly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIPRA Section 3(c)(2)(B) contained in a guidance package dated August 18, 1981 to summer date concerning the active ingredient 1-Naphtralene Acevic acid

Hamo of Pien

874 Company Number

11546

Greenwood Chemical Company P.O. Box 26 Greenwood, VA 22943

This firm or group of firms is referred to below as "my firm".)

(2) My firm is willing to develop and submit the data as required by that Motice, if necessary. Reserver. By firm would prefer to enter late an agreement with one of more other registrants to develop jointly, or to shees in the cost of developing, the following required items of data:
163.122-2: Effects on Aquatic Macrophytes 163.83-3: Teratogenicity

Residue Data: Crops-Apples, pears, pineapples, olives

Dissociation Data

163.122-2: Effects on Alago

163.72-1: Fish Acute IC 50 163.72-2: Acute Toxicity to Aquatic Invertabrates

163.122-1: Effects on Terrestrial Macrophytes

(3) My firm has offered in writing to enter into such an agreement, and has offered to be bound by an arbitration decision under PIFRA Section B(c)(2)(B)(111) if agreement on all terms could not be reached otherwise. - This offer was made to the following firms (s) on the following date (s):

Firm

Data of offer

Union Carbide Corporation

Letter - 10/07/82 Meeting between Mr. Robert Merrill and Union Carbide personnel - 3/82 Several telephone conversations by Mr. Merrill and Mr. C.C. Shipman with Union Carbide personnel. As of 10/26/82, Union Carbide said they would reply to our written request with two (2) weeks.

Bowever, none of those fire(s) accepted my offer.

(4) My fire requests that EFA not suspend the registration(s) of my fire's product(s), if any of the firms named in paragraph (3) above have agreed: """ to submit the data listed in paregraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must subsit the data to avoid suspension of its registration(s) under FIFRA Section 3(e)(2)(8).

October 28, 1982 a tod:

> Signagueel Clinton C. Shipman, Predident

> > (Typed)

NOV 3 0 1982

Greenwood Chemical Company State Highway 690 P.O. Box 26 Greenwood, VA 22943

Attention: B. Shannon Roberts

Gentlemen:

Subject: 1-Naphthalene Acetic Acid EPA Registration No. 11546-2

Your Submission Dated October 28, 1982

Testing Protocols

We have reviewed the submitted protocols and find that tests conducted according to these protocols would be acceptable. The submission of these completed tests would fulfill some of the data requirements outlined in the reregistration standard.

Sincerely yours,

Robert J. Taylor
Product Manager (25)
Fungicide-Herbicide Branch
Registration Division (TS-767C)

TS767C:RTAYLOR:DCR-04023:WANG-1362C:CBP:Raven:479-2013:11/29/82

Greenwood Chemical Company State Highway 690 F.O. BOX 26 Greenwood, VA 22943

Attention: Clinton C. Shipmen

Contlemen:

Subject: 1-Waphthaless Acetic Acid, Sodium Calt

EPA Registration No. 11546-1 1-Maphthalone Acetie held ZPA Engistration Bo. 11546-2 Your Subalesion of Hovember 2, 1982

NAA Beregistration

we are reterning the forms that accompanied your recent submission of November 2, 1982. These forms were not signed and campot be used in support of the registration process. Please complete and return the attached forms.

Eincorely yours,

a company

Robert J. Taylor Product Manager (25) Fungiciés-herbicide Branch Registration Division (TS-767C)

Attaclment

TS-767C:12-TAYLOR:DCR-04019:WANG-1343C:gmm:Raven:479-2013:11/26/82

NOV 16 1982

Ar. Clinton C. Shipman Greatwood Company Post Office Box 26 Greenwood. VA. 22943

Dear Mr. Shipman:

SUBJECT: Registration Status of:

1-Naphthaleneacetic ac1d, EPA Reg. No. 11546-1 1-Haphthaleneacetic ac1d, EPA Reg. No. 11546-2

In a certified mail letter dated October 1, 1982, you received a notice of intent to suspend registration of the subject products due to your failure to respond adequately to the terms in a Guidance Package from SPA dated August 8, 1981.

The record shows , however, that you requested a waiver from the need for submitting data dated Harch 19, 1982. The suspension letter should not have been sent before you were notified of the status of your valver request. Therefore, you may disregard the suspension notice.

Please note that the terms and conditions in the Guidance Package for naphthalaneacetic acid still exist and you are obligated to exercise one of the various options contained therein, now that your waiver request has been denied in our letter of October 25, 1982. It is our understanding that you are activaly engaged in preparing the necessary documents and will forward them in the near future.

Please accept our regrets for any impact the suspension notice may have caused.

Sincerely.

Douglas D. Campt, Director

Registration Division (TS-767C)

GREENWOOD CHEMICAL COMPANY P.O. Box 26 Greenwood, Virginia 22943 (703) 456-6832

November 2, 1982

Mr. Rober: V. Taylor
Product Manager 27
Registration Division (1767)
ENTEROMORY : PROTECTION AUGUST
HOLE Street S.U
Vashington, D.L. 20460

Dear Hr. Taylors

We have property and sent to you on October 26, 1962 copies of the protocols for the required toxicity data, which we led asked salvers. As seen as we receive an appear has to the their those will east with EPA's opposed, we will have licenses positions with these test.

So have pent as of Ortober 7, 1962 to Union Carridge a letter galding about working together to obtain this data, and we expect to receive an answer within two senies of Ortober 20, 1982. We are analysed to agree upon the sport of componention to Union involve until they tail us how much they are going to things up, if we are to reference their data, we have had several communication while them by telephone and he hotort Ferrill personally not with them so discuss this matter semiler this year. If we cannot agree upon a cost, we will have to any for analystance through additionally we are indicated this with Union Carvide, and a cost of a statement from he; hereafted the regular this with Union Carvide, and a cost of a statement from he; hereafted to an interpret to maintain our labels and have substituted some of the regulates data, and are in the process of doing further teating. He are stilling to be thatever is measured to maintain our labels and have substituted some of the regulates data, and are in the process of doing further teating. He are set in the process of doing further teating. He are not appearable for lateragent of Millingerse to Enter into an agreement with Other Degletzmate for lateragement of Data. We not proviously entailtied these forms, but her process over the process of the production of the process of the pr

We are also, naming yours copy of best results from left skeming the effects of our masts saids on fine. This mater contains how Alpha Maghingless Acetic Acid than may ground saids, sail, or stream could possible have in [t. It is from our plant oners as meet the requirem, grinders, drystallasts; and floors in this characters acid is contained. In this time the result show no harm to the first. This was done for the linguistant state Mater Control Bogrd and is part of our records with these. As wish to substitutes as a part of our record with the Electronic particles show the full strength sever had no illustrated and with the part of the first particles show the full strength sever had no illustrated and will not pass any size of a fish in the very small quantities had could get into the pass any size of a fish in the very small quantities had

Kr. Abbert J. Taylor Movember 2, 1962 Page 2

As previously stated, we have substitude some of the required data, are in the process of obtaining more as soon as so hear from MPA about the protectle end, we are williant to share the cost of any soult innel data, which we are in need of and do not have at the present time or have contracted to have done. We have had our registration since 1971, and have always done what was required of us to need the processary rules and regulations. We will continue to to this even when we are put under pressure from others trying to put us out of pushness and from those who are suppose to be there to help the small businesses:

We will be looking for your sarly reply about the protocols so we can continue to do what is necessary to maintain our registration.

Cordially yours.

Clinton C. Shipman, President

CCS/ber

Englosures i Appendix II-I

appudis 1115

Copy of Letter to Mr. Johnson, March 19, 1982

Copy of Mt. Robert Name 11's statement

Copy of Aqua-Air Laboratories, Inc. test results (Affects of

Vaste Vater on Plah)

cai Thomas R. Alimoeyk

March 19, 1982

Nr. Edwin G. Johanna Deputy Assistant Administrator for Postloide Programs Begintration Division (75-767) Office of Postloide Programs BW INOMINITAL PROTECTION ACTION Vashington, D.C. 20400

1-NAPWIHALAME ACETIC ACID
1-NAPWIHALAME ALETIC ACID GODIUM SALE

Mar Mr. Johnson:

Attached to this letter is our request for a mirer on requirements for embalting siditional date.

On the matter of data already submitted, we have recently not with Union Carbide personnel at Research Triangle, N.C. to discuss the data, which they have submitted imprier to register their fermulated predects. However, we are unable to reach an agreement with them to chape the dect, because they are insisting on our essenting pre-half of their expenses, which they estimate at \$250,000 to \$300,000. Such an assent of meany would be an impossible burder for a small company. We just cannot expense up with ever one-half of that expend.

In the meantime, Jaion Carbide Company has taken advantage of the law and has decided to become a producer of the basic product, 1-Rephtheless Acetic Acid. They have notified some of the means of MAA that they (Union Carbide) will wrive sharing of the cost of obtaining data, if the means (purchasers) will buy from Union Carbide. Such a mituation puts us at recovered Chapterlate at a disservantage, since we mannet use the law in such a manner. Cur position is that for a lamps company to use the law to their era advantage was not the purpose of the law. The law was not adopted to put small respense out of Samines, and make lamps companies - larger.

It is our desire and intention to continue as a preducer of i-Rayathaless Acetic A id, and its asting calt, and to are aching the EFA to help per...

Vest was rouse

Cliston C. Walyson, Procident

in bert Morrilli, Chemical Berliner ""

Nr. Dan Dackson

May 28, 1982

To: Greenwood Chemical Greenwood, Virvinia

From: Robert E. Kerr.11

Greenword, va. 2:43

Expenses for consulting on application to EPA for registration of NA..

Jonsulting \$50.00

Jelephone Expenses

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\$57.32

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Charal Engineer

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P. O. BOA 5601 @ 1229 A HARRIS 51 @ CHARLOTTESVILLE, VA. 22903 PHONE (801) 295-2716

GREENWOOD CHEMICAL COMPANY Greenwood, Virginia

ETHASSAY

Test Conditions: On July 15 and 16, 1976, a twenty-four hour static bioassay was conducted using blue gill sunfish fingerlings (Lepomis macrochirus in wastewater from the final lagoon at the Greenwood Chemical Company. The wastewater was used at full-strength and at various dilutions, made on a logarithmic scale with water from a nearby farm pond. The test was conducted in an air conditioned building at Greenwood Chemical Company using replicate 53 Liter (14 gallon) samples in plastic containers. The water was constantly aerated, keeping dissolved oxygen levels above 5 mg/l. The fish weighed 3 to 5 grams each, and five individuals were stocked per container, a rate of 2.7 to 3.5 Liters/gram of fish. The fish were supplied by The Perry Minnow Farm, Windsor, Virginia.

No fish mortality due to the toxicity of the water was recorded either with the full-strength wastewater or with the diluted water; however, one fish jumped out and excired. The fish displayed no obvious irritability or erratic behavior, especially when first introduced into the containers.

Table of Bioassay Posults

| | nilu | tion | | | |
|-----------------------------|--------------|--------------|------------|--------------------|---------------------------------------|
| Container # 1 2 3 4 5 6 7 8 | % Wastewater | * Pond Water | <u>Ifq</u> | Initial No of Fish | . Final No. of Fish |
| 1 | 100 | 0 | 9.5 | 5 | 4 * |
| 2 | 100 | 0 | 9.4 | 5 | 5 |
| 3 | 87 | 13 | 9.3 | 5 | • 5 |
| 4 | 87 | 13 | 9.3 | 5 | 5 |
| 5 | 75 | 25 | 8.8 | 5 | 5 |
| 6 | 75 | 25 | 8.8 | 5 | 5 |
| 7 | 65 | 35 | 8.5 | 5 | 5 5 5 |
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| 9 | 0 | 100 | 7.9 | 5 | 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 |
| *One Fich in | mned out | | | | 0.0 |

*One fish jumped out.

Based on this twenty-four hour static bioassay, the water tested from the final lagoon at Greenwood Chemical Company was found to be non-toxit.

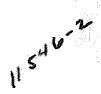
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Date November 22,1982 Subject: EPA Registration Number: 11546-2. «- Naphalene autie and Protocals) From: Delaris J. Staham (9 11/21/82 20: Robert Taylor (25) D applicant: Sheenwood Chemical Company P.O. BOX 20 State Highway 690 Greenword Vinginia 22943 Background: Submitted protocols for aute Dermal britation and Dermal Sensitivition Studies to be conducted on & Raptholene audie and by Bioassay Systems organistion. Submitted a protocal for the aute Inhalation Itudy to be conducted on a - Maphalen adli acid by Bio/dynamus In. Recommendations: (1) SHB fill finds him perfocals acceptable to necessary to meet requirements of conditional registration of this product Please note, However that all sudies meent be condertal on the Romuelelian

State Highway 690 P. O. Box 26 Greenwood, Virginia 22943

Telephone 703 456-6832



October 28, 1982

Mr. Robert J. Taylor
Registration Division (TS-767C)
Office of Pesticide Programs
ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Dear Mr. Taylor:

We have enclosed copies of the protocols to be followed in the testing of 1-Naphthalene Acetic Acid, which we received from Bioassay Systems Corporation of Woburn, MA.

We would appreciate your immediate attention to these so that we may inform Bicassay to continue with the necessary data testing. Therefore, your earliest reply would be appreciated.

If you have any questions, please do not hesitate to contact Mr. Clinton C. Shipman or myself.

Cordially yours,

B. Skennon Pobert

B. Shannon Roberts

sr

Enclosures: Protocols for testing for 1-Naphthalene Acetic Acid



BIONSSAY SYSTEMS CORPORATION

Study Protocol

I. STUDY IDENTIFICATION:

- A. <u>Title of Study</u>: Acute Oral ID₅₀ Determination, Primary Eye Irritation, Primary Dermal Irritation, Acute Dermal Toxicity, and Dermal Sensitization Tests.
- Purpose of Study: To evaluate the potential of the test B. sample to produce oral toxicity to rats, toxicity to rabbits irritation to the eye and skin of rabbits. The dermal sensitization test is performed to evaluate the potential of the sample to produce delayed-type contact sensitization after multiple topical applications.

C. Project Numbers:

1. BSC Project No.: 11387

2. Sponsor Project No.: NAA-1

II. STUDY MANAGEMENT:

A. Sponsor Identification:

1. Name: Greenwood Chemical Company

2. Address: P. O. Box 26, State Highway 690 Greenwood, VA 22943

3. Telephone No.: (703) 456-6832

4. Study Director: Mr. Clint Shipman

B. <u>Testing Laboratory Identification</u>:

1. Name: Bioassay Systems Corporation

2. Address: 225 Wildwood Avenue Woburn, MA 01801

3. Telephone No.: (617) 933-9229

4. Study Director: Jane B. Goodband

C. Quality Assurance Manager: Mr. Peter Mione

III. PROPOSED SCHEDULE:

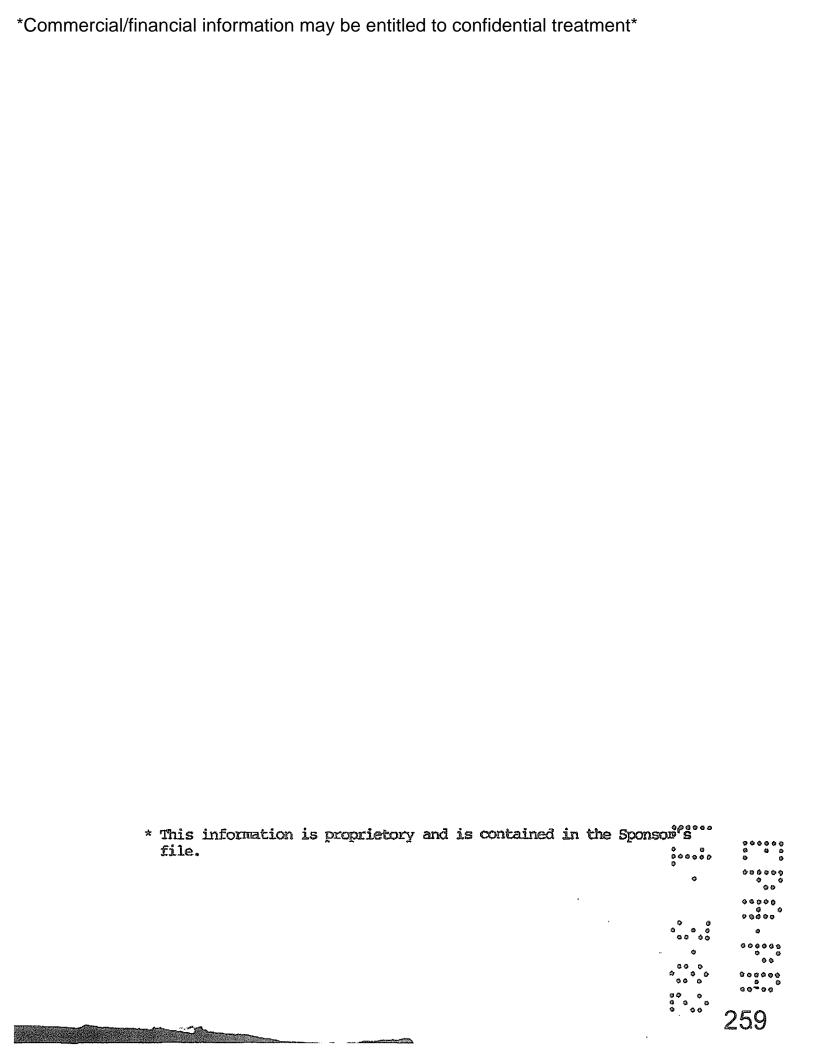
Oral Dermal Skin Eye Sensitizātion

A. Testing Initiated:

B. Testing Completed:

C. Completion of

FIRST WEEK-



V. PREPARATION OF TEST SAMPLE:

The test sample(s) will be prepared according to the methods agreed upon by the BSC Study Director and the Sponsor.

The preparation procedures are indicated below:

1. Acute Oral LD50 Determination.

The sample is dissolved in an appropriate solvent prior to administration. The vehicle used will be specified in the form of a protocol amendment.

Primary Eye Irritation Test.

The sample is administered to the eye in the form of a powder. If the sample is not in the form of a powder, it will be ground with a mortar and pestle.

3. Primary Dermal Irritation Test.

0.5g of sample is weighed on a top loading balance and then moistened with 0.9% sodium chloride prior to application.

4. Acute Dermal Toxicity Study.

The calculated amount of sample (based on a dose of 2000 mg/kg) is weighed on a top loading balance. The sample is moistened with 0.9% sodium chloride prior to application.

5. Dermal Sensitization Test.

- a. Control: 1-chloro 2,4-dinitrobenzene in 80% ethanol. A 0.5% (w/v) solution of 1-chloro 2,4-dinitrobenzene in 80% ethanol is prepared.
- b. Test sample: The powdered sample is moistened prior to application with 0.9% sodium chloride.



VI. REPORT:

At the termination of the study, a report will be prepared describing the objectives of the study, sample preparation, experimental design, textual and tabular presentation of results, conclusions and quality assurance information.

VII. RECORDS TO BE RETAINED:

All original data and a copy of the final report will be retained for not less than five years after completion of the study and stored in the Bioassay Systems archives. The report will be made available for inspection only upon request by authorized representatives of the Sponsor. The Sponsor will be notified before final disposition of these items.

VIII. SAMPLES TO BE RETAINED:

The samples will be stored at appropriate conditions for a period of 4 weeks following submission of the final report, at which time they will be discarded. For studies lasting more than 4 weeks duration, reserve samples will be retained for a period lasting no less than 5 years. If requested, the samples will be returned to the Sponsor at his expense.

IX. GOOD LABORATORY PRACTICES:

This study will be conducted according to FDA Good Laboratory Practice Regulations (21 CFR 58.1-58.219, 1979).

X. QUALITY ASSURANCE:

This study will be monitored under provisions of the BSC Quality Assurance Program and the final report will be reviewed by BSC Quality Assurance Unit personnel.

XI. ALTERATIONS OF STUDY DESIGN:

Alterations of this protocol may be made as the study progresses. No major changes in the protocol will be made without the consent of the Sponsor. In the event the Sponsor authorizes a protocol change verbally, such change will be documented and signed by the Study Director and Quality Assurance Officer and will be maintained with the protocol. These protocol amendments will be included in the final report.

90 4 8 9 9

XII. Evaluation of Sample Composition and Stability

1. Does the Sponsor request that dosage analysis be performed?

YES

WO

2. Does the Sponsor request that stability analysis of the test and control articles under conditions of administration be performed if this information is not supplied?

YES

NO



Protocol Approval

| Bioassay Systems Corporation | • |
|--|---------------------|
| By: Jan & Coordbard | |
| By: <u>Jane & Coordinand</u> Title: <u>Stacky Director</u> | |
| Date: 10/18/82 | |
| Sponsor | |
| By: | |
| Title: | |
| Date: | |
| BSC Quality Assurance | |
| Protocol Content | Protocol Completion |
| By: Yneyory A. Korace | |
| By: Yneyory A. Rorace Title: D. A. Officer | - |
| Date: 10/20/8/ | |
| | |
| Telephone Authorization to Initiate Work | |
| Sponsor Representative: Mr. Clint Shipman | |
| Sponsor Telephone No.: (703)456-6832 | |
| Date of Call: October 18, 1982 | |

BIOASSAY SYSTEMS CORPORATION

Test Protocol

1.0 Title of Test: Dermal Sensitization Test

2.0 References:

- 2.1 Federal Register, Vol. 43, No. 163.81-6, Tuesday, August 22, 1978.
- 2.2 Draize, J.H. (1965, Appraisal of the Safety of Chemicals in Foods, Drugs, and Cosmetics. Association of Food and Drug Officials of the U.S. Topeka, KS, pp. 49-52).

3.0 Purpose of Test:

To evaluate the potential of a test sample to produce delayed hypersensitivity to guinea pigs. The route of administration is specified in reference 2.1.

- 4.0 Supervisory Personnel of Test:
 - 4.1 Manager: Jane B. Goodband
- 5.0 Materials:
 - 5.1 Test animals:
 - 5.1.1 Name: Guinea pig
 - 5.1.2 Species: Cavia porcellus
 - 5.1.3 Strain: Duncan Hartley
 - 5.1.4 Supplier: The source of the animals used in each assay is specified in the final report.

 Animals used for each assay are obtained from a single source.
 - 5.1.5 Age at start of study: 3 to 5 weeks
 - 5.1.6 Weight at start of study: 300 to 500 grams
 - 5.1.7 Sex: Males
 - 5.1.8 Number: 10/test sample 10/positive control
 - Justification for selection of test animals: The guinea pig is a reliable model for indicating potential toxic reactions. It has been ased extensively for such studies and consequently, a large body of data is available for reference purposes.

5.1.10 Identification:

Each animal is given a number upon receipt from the supplier. The number is placed on an animal ID card and appropriate holes and notches are made in each ear with a membrane ear punch.

5.1.11 Quarantine period: Sufficient amount of time to

determine the health status of

the animals.

5.1.12 Husbandry:

5.1.12.1 Housing: One guinea pig per cage.

5.1.12.2 Food: Charles River Guinea Pig Chow.
Periodic examination of animal

food is conducted according to BSC, SOP entitled "Examination of Laboratory Animal Chow for

Microbial Contamination".

5.1.12.3 Water: Untreated from municipal water

supply, ad libitum. The municipal water is periodically examined according to BSC, SOP's entitled "Examination of Water for Coliform Bacteria" and "Periodic Chemical and Mutagen Analysis of Water Used at

Bioassay Systems".

5.1.12.4 Light: 12-hour light/dark cycle (lights

on 7AM to 7PM).

- 5.1.12.5 Temperature: 74°F ± 5°F
- 5.1.12.6 Humidity: 50% ± 15%
- 5.1.12.7 Air Flow: 12-16 complete changes of 100%

fresh air hourly.

- 5.2 Reagents:
- 5.3 Test controls:
 - 5.3.1 Negative: Not required
 - 5.3.2 Positive: 0.5% (w/v) solution of 1-chloro 2,4-dinitrobenzene,in 80% ethanol...

6.0 Test Procedure:

- 6.1 Upon receipt, the health status of the animals is inspected according to BSC, SOP entitled "Assessment of Health Status at Time of Animal Receipt". The animals are placed into appropriately labelled cages.
- 6.2 The animals are weighed and randomized according to BSC Standard Operating Procedure "Randomization of animals using the random numbers chart".
- 6.3 The hair is removed by clipping and then shaving from a strip running from flank to trunk along the side of each animal. This procedure shall be repeated as necessary.
- 6.4 After preparation of the test animals, 0.5 grams of the test sample previously moistened with 0.9% sodium chloride, is applied to a gauze pad. The gauze pad is secured to the test site with surgical tape. The trunk of the animal is wrapped with plastic wrap and then stockinette to prevent removal of the patches by the animal.
- 6.5 Topical applications of the test sample will be performed 3 times weekly on alternate days for 3 weeks. A total of 10 applications shall be made.
- 6.6 The positive control will be applied in the same manner as for the test sample.
- 6.7 Following the 10th sensitizing treatment, the test and control animals will be set aside for 2 weeks after which they will be challenged by a final application of 0.5 grams.
- 6.8 Erythema, edema and other lesions shall be scored at 24 hours and 48 hours after each application according to Draize.

7.0 Date Evaluation

- 7.1 Calculate the average score from all sensitizing treatments and the average score for the challenge treatment.
- 7.2 If the value for the challenge reading is substantially higher than for the average of the twenty original readings, the sample can be considered to have produced sensitization.

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BIOASSAY SYSTEMS CORPORATION

Test Protocol

- 1.0 Title of Test: Acute Dermal Toxicity Study in Rabbits
- 2.0 References:
 - 2.1 Federal Register, Vol. 43, No. 163.81-2. Tuesday, August 22, 1978.
- 3.0 Purpose of Test:

To evaluate the potential of a test sample to produce toxicity and death to a group of 10 rabbits within 14 days when applied topically to the skin. The dermal route of exposure has been selected to determine the possible effects of the dermal exposure to the test sample by humans.

- 4.0 Supervisory Personnel of Test:
 - 4.1 Manager: Jane B. Goodband
- 5.0 Materials:
 - 5.1 Test animals:
 - 5.1.1 Name: Albino rabbit
 - 5.1.2 Species: Orycetolagus cuniculus
 - 5.1.3 Strain: New Zealand White
 - 5.1.4 Supplier: The source of the animals used in each assay is specified in the final report.

 Animals used for each assay are obtained from a single source.
 - 5.1.5 Age at start of study: 10 to 22 weeks
 - 5.1.6 Weight at start of study: 2.3 to 3.5 kilograms
 - 5.1.7 Sex: Males and Females
 - 5.1.8 Number: 5 of each sex

Justification for selection of test animals: The rabbit is a reliable model for indicating potential toxic reactions. It has been used extensively for such studies and consequently a large body of data is available for reference purposes. The strain chosen is genetically defined so the variability among individual animals is minimized.

5.1.10 Identification:

Each animal is given a number upon receipt from the supplier. The number is placed on an animal ID card and marked in the ear of that animal with an indelible marker.

5.1.ll Quarantine period: Sufficient amount of time to determine the health status of the animals.

5.1.12 Husbandry:

5.1.12.1 Housing: One rabbit per cage

5.1.12.2 Food: Charles River Rabbit Formula.
Periodic examination of animal food is conducted according to BSC, SOP entitled "Examination of Laboratory Animal Chow for Microbial Contamination".

5.1.12.3 Water: Untreated from municipal water supply, ad libitum. The municipal water is periodically examined according to BSC, SOP's entitled "Examination of Water for Coliform Bacteria" and "Periodic Chemical and Mutagen Analysis of Water Used at Bioassay Systems".

5.1.12.4 Light: 12-hour light/dark cycle (lights on 7AM to 7FM).

5.1.12.5 Temperature: 74°F ± 5°F

5.1.12.6 Humidity: 50% ± 15%

5.1.12.7 Air Flow: 12-16 complete changes of 100% fresh air hourly.

5.2 Test controls: N/A

6.0 Test Procedure:

- 6.1 Upon receipt, the health status of the animals is determined according to BSC, SOP entitled "Assessment of Health Status at Time of Animal Receipt". The animals are placed into appropriately labelled cages.
- 6.2 Weigh each animal prior to administration of the test substance and record on the data record sheet.
- 6.3 Prior to dosing, approximately 10% of the animal's body surface will be clipped free of hair.
- 6.4 The animals are further prepared by making epidermal abrasions over the area of exposure with a fine file.
- 6.5 A patch is prepared by covering a 6" x 6" gauze pad with plastic wrap.
- 6.6 Each animal will receive a topical application of the sample at 2 grams/kilogram body weight. The sample is moistened with 0.9% sodium chloride, applied to the gauze pad, and secured to the test site with surgical tape. The entire trunk of the animal is wrapped with stockinette to prevent removal of the patches by the animal.
- 6.7 Return each animal to its cage and provide food and water ad libitum.
- 6.8 Leave patches on for a period of 24 hours.
- 6.9 At the end of the exposure period, remove the patches and gently wipe the test material off the skin.
- 6.10 Animals shall be observed frequently during the day of administration of the test sample and twice daily thereafter for death and signs of toxicity. The following shall be recorded: Nature, onset, severity and duration of each toxic and pharmacologic sign, such as abnormal or unusual cardiovascular, respiratory, excretory, behavioral, or other activity, as well as signs indicating an adverse effect on the central nervous system (paralysis, lack of coordination, staggering); pupillary reaction; and time animal found dead. These findings will be summarized in the final report.

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- 6.11 The weight of each animal shall be determined on the day of dosing, weekly thereafter, and at death.
- 6.12 All animals surviving at the termination of the observation period shall be sacrificed. Animals dying during the course of the study, shall be subjected to a complete gross necropsy following their death. All abnormalities shall be recorded.

7.0 Data Evaluation

- 7.1 If data based on testing with 5 animals per sex with abraded skin are submitted showing that the ${\rm ID}_{50}$ is greater than 2 g/kg for the 24 hour contact period, no further testing at other dose levels is necessary. If mortality is produced, a Range Finder and Dermal ${\rm ID}_{50}$ will be performed if requested by the Sponsor.
- 7.2 Any serious lesions upon necropsy are described.
- 7.3 Observation period animal found dead.
- 7.4 Measure pH value of the test sample if appropriate.

BIOASSAY SYSTEMS CORPORATION

Test Protocol

- 1.0 <u>Title of Test</u>: Acute Oral LD₅₀ Determination
- 2.0 References:
 - 2.1 FIFRA Guidelines Federal Register, Vol. 43, No. 163.81-1, August 22, 1978.
- 3.0 Purpose of Study:

To determine by oral administration the dose that is lethal to one-half of an animal population. This value is defined as an ${\rm LD}_{50}$. The oral route of exposure has been selected to determine the possible effects of the oral ingestion of the test sample by humans.

- 4.0 Supervisory Personnel of Test:
 - 4.1 Manager: Jane B. Goodband
- 5.0 Materials:
 - 5.1 Test animals:
 - 5.1.1 Name: Albino Rat
 - 5.1.2 Species: Rattus norvegicus
 - 5.1.3 Strain: Sprague-Dawley
 - 5.1.4 Supplier: The source of the animals used in each assay is specified in the final report.

 Animals used for each assay are obtained from a single source.
 - 5.1.5 Age at start of study: 6 to 10 weeks
 - 5.1.6 Weight at start of study: 175 to 300 grams
 - 5.1.7 Sex: Males and Females
 - 5.1.8 Number: At least 30
 - Justification for selection of test animals: The rat is a reliable model for indicating potential toxic reactions. It has been used extensively: for such studies and consequently a large body of data..... is available for reference purposes.

5.1.10 Identification:

Each animal is given a number upon receipt from the supplier. The number is placed on an animal ID card and marked in each ear with appropriate notches and holes with a membrane ear punch.

5.1.11 Quarantine period: Sufficient amount of time to determine the health status of the animals.

5.1.12 Husbandry:

5.1.12.1 Housing: 5 per cage.

5.1.12.2 Food: Charles River R-M-H 3000. Periodic examination of animal food is conducted according to BSC, SOP entitled "Examination of Laboratory Animal Chow for Microbial Contamination".

5.1.12.3 Water: Untreated from municipal water supply, ad libitum. municipal water is periodically examined according to BSC, SOP's entitled "Examination of Water for Coliform Bacteria" "Periodic Chemical and Mutagen Analysis of Water Used at Bioassay Systems".

12-hour light/dark cycle (lights 5.1.12.4 Light: on 7AM to 7PM).

Temperature: 74°F ± 5°F 5.1.12.5

5.1.12.6 Humidity: 50% ± 15%

5.1.12.7 Air Flow: 12-16 complete changes of 100% fresh air hourly.

5.2 Vehicle controls:

To be specified in the form of a protocol amendment. 5.2.1

6.0 Test Procedure:

- 6.1 Upon receipt, the health status of the animals is determined according to BSC, SOP entitled "Assessment of Health Status at Time of Animal Receipt". The animals are placed into appropriately labelled cages. Animals are randomized prior to testing utlizing BSC Standard Operating Procedure "Randomization of animals using the random numbers chart".
- 6.2 For the LD50 Determination, at least 30 male and 30 female rats are used, 5 of each sex per dose group. There will be 5 dose levels and one control.
- 6.3 Label each animal and its cage.
- 6.4 Fast animals from food the night prior to dosing.
- 6.5 Weigh each animal prior to administration of the test sample and record weight on the Data Record Sheet.
- 6.6 Dose levels to be used will be based on the results of the Acute Oral Range Finding Determination. If data based on testing with at least 5 animals per sex are submitted showing that no mortality is evident at 5 g/kg, no further testing at other dose levels is necessary. Prior to initiation of the ID₅₀ Determination, dose levels will be chosen and specified in the form of a protocol amendment.
- 6.7 Administer the test sample suspension or solution orally by gavage using a large ball tip needle attached to a plastic or glass syringe.
- 6.8 Return each animal to its cage and provide food and water ad libitum.
- 6.9 Observe the animals frequently during the day of dosing and twice daily thereafter for 14 days recording any deaths or signs of toxicity. Weight of dead animals are to be recorded as soon after death as possible. All animals are to be necropsied for gross internal observations.
- 6.10 Nature, conset, severity, and duration of all gross or visible toxic or pharmacological effects such as abnormal or unusual cardiovascular, respiratory, excretory, behavioral, of officer activity, as well as signs indicating an adverse effect on the central nervous system (paralysis, lack of coordination, staggering); pupillary reaction; and time animal found thead will be recorded. These findings will be summarized in the final report.

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6.11 The weight of each surviving animal must be determined on days 0, 7 and 14.

7.0 Data Evaluation

- 7.1 ID50 and 95% confidence limits are determined for the combined population (and for each sex if requested by the sponsor) by Karber's Method (revised) in <u>Probit Analysis</u> by D. J. Finney. 2nd Edition. University Press, Cambridge, 1952.
- 7.2 Any serious lesions are described.
- 7.3 Tabulation of response data by sex and dose level.
- 7.4 Observation period animal found dead.
- 7.5 Dose-response curve and slope.
- 7.6 Measure pH value of the test sample if appropriate:

BIOASSAY SYSTEMS CORPORATION

Test Protocol

1.0 Title of Test: Primary Dermal Irritation Test

2.0 References:

- 2.1 FIFRA Guidelines Federal Register, Vol. 43, No. 163.81-5, August 22, 1978.
- 2.2 Draize, J. H., 1965. Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics. Association of Food and Drug Officials of the U.S., Topeka, KS, pp. 49-52.

3.0 Purpose of Test:

To determine the potential of a test sample to produce irritation to the skin when applied topically. The topical route of exposure has been selected to determine the possible effects of the test sample to the skin of humans.

4.0 Supervisory Personnel of Test:

4.1 Manager: Jane B. Goodband

Name: Albino rabbit

5.0 Materials:

5.1 Test animals:

5.1.1

| 5.1.2 | Species: Orycetolagus cuniculus |
|-------|--|
| 5.1.3 | Strain: New Zealand White |
| 5.1.4 | Supplier: The source of the animals used in each assay is specified in the final report. Animals used for each assay are obtained from a single source. |
| 5.1.5 | Age at start of study: 10 to 22 weeks |
| 5.1.6 | Weight at start of study: 2.3 to 3.5 kilograms |

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|-------|--------------|--------------|----------------|
| 5.1.7 | Sex: Males | | \$ 6 \$ |
| 5.1.8 | Number: 6 | | ବ୍ର ଓ ଜଣ |
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Justification for selection of test animals: The rabbit is a reliable model for indicating potential toxic reactions to the skin. It has been used extensively for such studies and consequently a large body of data is available for reference purposes. The strain chosen is genetically defined so the variability among individual animals is minimized.

5.1.10 Identification:

Each animal is given a number upon receipt from the supplier. The number is placed on an animal ID card and marked in the ear of that animal with an indelible marker.

5.1.11 Quarantine period: Sufficient amount of time to determine the health status of the animals.

5.1.12 Husbandry:

5.1.12.1 Housing: One rabbit per cage

5.1.12.2 Food: Charles River Rabbit Formula.

Periodic examination of animal food is conducted according to BSC, SOP entitled "Examination of Laboratory Animal Chow for Microbial Contamination".

5.1.12.3 Water: Untreated from municipal water supply, ad libitum. The municipal water is periodically examined according to BSC, SOP's entitled "Examination of Water for Coliform Bacteria" and "Periodic Chemical and Mutagen Analysis of Water Used at Bioassay Systems".

5.1.12.4 Light: 12-hour light/dark cycle. (lights on 7AM to 7PM).

5.1.12.5 Temperature: 74°F ± 5°F

5.1.12.6 Humidity: 50% 2 15%

5.1.12.7 Air Flow: 12-16 complete changes of 100% fresh air hourly. "...".

5.2 Test controls:

5.2.1 Negative: cotton gauze

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6.0 Test Procedure:

- 6.1 Upon receipt, the health status of the animals is determined according to BSC, SOP entitled "Assessment of Health Status at Time of Animal Receipt". The animals are placed into appropriately labelled cages.
- 6.2 For this test, 6 animals are used for each test substance.
- 6.3 Label each animal and its cage.
- 6.4 Weigh each animal prior to administration of the test substance and record on the data record sheet.
- 6.5 Clip hair from sides of animals.
- 6.6 Abrade the entire left side of the animal with a fine file.
- 6.7 Introduce 0.5 grams of the sample (previously moistened with saline) onto a 1" x 1" gauze pad. Secure the pad to the test site with surgical tape. Four pads with test material are used per animal, two on normal skin (right side) and two on the abraded skin (left side).
- 6.8 Place one 1" x 1" gauze pad on each side; one on the abraded side and one on the unabraded side for the control.
- 6.9 Wrap the entire trunk of the animal first with an impervious covering such as plastic wrap and then with stockinette to prevent removal of the patches by the animal and evaporation of the sample.
- 6.10 Return each animal to its cage and provide food and water ad libitum.
- 6.11 Leave patches on for a period of 24 hours.
- 6.12 At the end of the exposure period, remove the patches and wipe skin to remove any remaining test substance. Observe and score test and control sites at 24 and 72 hours. If irritation persists, observe the site daily ungite all irritation subsides or is obviously irreversible.

7.0 Data Evaluation

7.1 Observe and score responses at 24 and 72 hours post treatment. """ use the dual erythema/edema scale of Draize et. al. . Add: the average value of erythema responses at 24 and 72 hours for intact skin to the average values on abraded skin at 24 and 72 hours, (total of 4 values before addition). Similatly and contact the values for edema formation at 24 and 72 hours for intact and abraded skin (4 values). The "value" recorded for each reading is the average value of the six or more animals subject to the test. The sum of the eight values is divided

by 4 to give the Primary Irritation Score. Primary Irritation indexes of 2 or less are only mildly irritating: whereas those with indexes from 2 to 5 are moderate irritants, and those with scores above 6 are considered severe irritants.

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BIOASSAY SYSTEMS CORPORATION

Test Protocol

1.0 Title of Test: Primary Eye Irritation Test

2.0 References:

- 2.1 FIFRA Guidelines Federal Register, Vol. 43, No. 163.81-4, August 22, 1978.
- 2.2 Draize, J. H., 1965. Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics. Association of Food and Drug Officials of the U.S., Topeka, KS, pp. 49-52.

3.0 Purpose of Test:

To evaluate the potential of a test sample to produce irritation to the eye and surrounding tissues after topical administration. The topical route of administration has been selected to determine the possible effects of the test sample to the eye of humans.

4.0 Supervisory Personnel of Test:

4.1 Manager: Jane B. Goodband

5.0 Materials:

5.1 Test animals:

| 5.1.1 | Name: Albino rabbit | | |
|-------|--|---------------------|---|
| 5.1.2 | Species: Orycetolagus cuniculus | | |
| 5.1.3 | Strain: New Zealand White | * | |
| 5.1.4 | Supplier: The source of the animals used in assay is specified in the fina Animals used for each assay are from a single source. | l report. | |
| 5.1.5 | Age at start of study: 10 to 22 weeks | 9 | 6 |
| 5.1.6 | Weight at start of study: 2.3 to 3.5 kilog | rans | g |
| 5.1.7 | Sex: Males | 6 6 6 6 60 66 | 6 |
| 5.1.8 | Number: 9 | * | 4 |

Justification for selection of test animals: The rabbit is a reliable model for indicating potential toxic reactions to the eye. It has been used extensively for such studies and consequently a large body of data is available for reference purposes. The strain chosen is genetically defined so the variability among individual animals is minimized.

5.1.10 Identification:

Each animal is given a number upon receipt from the supplier. The number is placed on an animal ID card and marked in the ear of that animal with an indelible marker.

5.1.11 Quarantine period: Sufficient amount of time to determine the health status of the animals.

5.1.12 Husbandry:

5.1.12.1 Housing: One rabbit per cage

5.1.12.2 Food: Charles River Rabbit Formula.

Periodic examination of animal food is conducted according to BSC, SOP entitled "Examination of Laboratory Animal Chow for Microbial Contamination".

5.1.12.3 Water: Untreated from municipal water supply, ad libitum. The municipal water is periodically examined according to BSC, SOF's entitled "Examination of Water for Coliform Bacteria" and "Periodic Chemical and Mutagen Analysis of Water Used at Bioassay Systems".

5.1.12.4 Light: 12-hour light/dark cycle. (lights on 7AM to 7FM).

5,1.12.5 Temperature: 74°F ± 5°F

5.1.12.6 Mumidity: 50% ± 15%

5.1.12.7 Air Flow: 12-16 complete changes of JOD's fresh air hourly. "...".

5.2 Test controls: N/A

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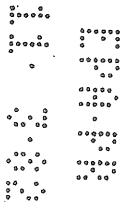
6.0 Test Procedure:

- 6.1 Upon receipt, the health status of the animals is determined according to BSC, SOP entitled "Assessment of Health Status at Time of Animal Receipt". The animals are placed into appropriately labelled cages.
- 6.2 Label each animal and its cage.
- 6.3 Examine eyes of all animals using fluorescein techniques at least 24 hours prior to treatment.
- 6.4 Weigh animals immediately prior to treatment and record.
- 6.5 Administer 0.1 gram of the sample on the everted lower lid of the right eye. Smaller quantities may be used when 0.1 gram of the solid cannot feasibly be administered to the eye.
- 6.6 The upper and lower lids are gently held together for 1 second before releasing to prevent loss of material. The other eye serves as the untreated control.
- 6.7 The treated eyes of six rabbits shall remain unwashed.
- 6.8 The remaining three rabbits receive test material and then the treated eyes are flushed for one minute with lukewarm water starting no sconer than 20-30 seconds after instillation.
- 6.9 Return the animals to their cages and give them food and water ad libitum.
- 6.10 Reading of ocular lesions must be made at 24, 48 and 72 hours after treatment and at 4 and 7 days after treatment. Readings must be made every 3 days thereafter, if injury persists, for at least 21 days after treatment or until all signs of reversible toxicity subside.
- 6.11 Grading and scoring of irritation are to be performed in accordance with BSC SOP entitled "Scale for Scoring Ocular Lesions According to FIFRA and TSCA Guidelines".
- 6.12 The most serious effects, such as pannus or blistering of the conjunctive and other effects indicative of corrosive action must be recorded separately.

7.0 Data Evaluation

- 7.1 The primary eye irritation score at 24, 48, and 72 hours and at 4 and 7 days and any other readings.
- 7.2 Total eye irritation scores for each animal are calculated for each time of observation by adding the individual schles for cornea, iris and conjunctiva.

- 7.3 The mean eye irritation score and range for each group (lavaged and not lavaged) is computed.
- 7.4 Any serious lesions are described.





UPPERMIN N

To be replaced by completed TEST AND/OR CONTROL MATERIAL Form or appropriate MARX INC INFORMATION alternate supplied by sponsor upon authorization of study

This form is designed to specify test substance handling and disposition instructions and to provide procedures (if known) in case of accidental exposure to the substance. As with all data, this information will be continued with the study or studies union only to common involved with the study or studies union only.

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THE PERSON (2)

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Western

October 27, 1982

Mr. Thomas E. Admanyk
Segistration Ulvision (*5-7670)
Office of Festicide Programs
U.S. ENVISONSHEAR PROFESTION ACRES
401 H Street, S.F.
Machington, D.C. 25-60

Dear Nr. Missosyba

In our earlier cartifies letter of this month, I intoress you that we had written to Union Carbide with a cartified letter trying to cooperate still them. We had not heard from them as of Coboten 20. 1002, so I called Mr. Sobert Devilde, and he informed so that is should here to pay it allies for shall cooperation in the locative date. There were other discussions that I son't mention at this lise, but he did say that he had required our certified letter and sould give these answer from his laupure which the sent two weeks. This gentlemen does not realize or would not admit that section and index Darada violated Mr. laup to matil August 1962, Mr. Jewilde reasoners as that Union Carbide was soing to put up out of the business of membrackering lefertheless. Section Acid.

With me alternative, we have notified the Small Business Administration of our mituation. Sets use of the fact that the Gmall Business Administration has a Financial interest in Opsenscos Sheetost Company, this situation will be straightened out:

Cordally yours,

Clinton & Bipsen, Prosident

008/ar

ec: hobert J. Taylor -

007 25 1982

Mr. Clinton C. Shipman President Greenwood Chemical Company State Highway 690 Greenwood, Virginia 22943

Dear Mr. Shipman:

This letter is in reply to your letters of October 6 and 7, 1982. We have considered your request for waiver of the data requirements for the acute data gaps set fourth in the Naphthalene Acetic Acid Standard.

A data requirement may be waived if it is established that the composition, degradability, proposed patterns of use and such other chemical or physical properties of the pesticide are fundamentally different from the factors considered by the Agency in the establishment of the data requirement. A review of your data waiver request indicates no scientific basis for such a waiver. Further, the Agency has received a commitment from another company to complete and submit the generic data as set forth in the Standard. The acute toxicity studies for which waivers have been requested must be developed and submitted to the Agency.

Please note that the studies that you intend to complete will not fulfill the total data requirements given in the Standard. All data gaps must be satisfied by a commitment to perform the additional studies or the submission of a statement to offer to pay for reliance on previous submitted data.

If you do not meet the requirements as given above, your product will be suspended as stated in our letter of October 1, 1982.

Robert Taylor Product Manager 25 Pungicide-Herbicide Branch Registration Division (TS-767C)

Cotobor 6. 1982

Director, Registration Civision (55-7074) ATTENTION: ROBERT 1. TAYLOR PH-25 Office of Pesticide Programs H.S. ENVIRONMENTAL PROTECTION AGENCY 401 k Street, S.W. Verbingon, D.U. 20460

lear dr. Jeylori

In our meeting sith it, almostly or very informed that it scale take that For our request for extremist certain date. Until we get an answer on our selver request, we associa not pursue obtaining the require outs top those lies state as request walver on. Mr. Man-cays, else, stated that our requestration would not be neith up because of our latters to enter the season reason.

AND CONTRACT TO SELECT AND SELECT

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These are the very come that he delanders has informed in her to proceed further in obtaining any additional information until he required the decision about our salver request.

Cordially yours,

Enclosures 21

Dan Jakeon. 000 T.E. Alaboryk



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Certified Mail

OCT 11982

Subject: Suspension of Pesticide Products Due to Failure to Respond to the Requirement for Submission of Data Stated in the Guidance Package for Naphthaleneacetic Acid

Dear Registrant:

This is to give you notice that the Agency is suspending your registrations for the pesticide products listed in Attachment I at the end of 30 days from the receipt of this letter. The Agency's authority for this suspension action is found in section 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (FIFRA), which provided that:

"...if the Administrator determines that a registrant, within the time required by the Administrator, has . failed to take appropriate steps to secure the data required under this subparagraph, to participate in a . procedure for reaching agreement concerning a joint data development arrangement under this subparagraph or in an arbitration proceeding as required by this subparagraph, or to comply with the terms of an agreement or arbitration decision concerning a joint data development arrangement under this subparagraph, the Administrator may issue a notice of intent to suspend such registrant's registration of the pesticide for which additional data is required. The Administrator may include in the notice of intent to suspend such provisions as the Administrator deems appropriate concerning the continued sale and use of existing stocks of such pesticide. Any suspension proposed under this subparagraph shall become final and effective at the end of thirty days from receipt by the registrant of the notice of intent to suspend, unless during that time a request for hearing is made by a person ad-

GREENWOOD CHEMICAL COMPANY

P. O. Son 26

GREENWOOD, VIRGINIA 22943 State Highway 660

Phone: 703/456-6832

PRODUCT INFORMATION BULLETIN

SPECIFICATION SHEET

1-Naphthalene Acetic Acid

Assay

Melting Point

Ash

Color

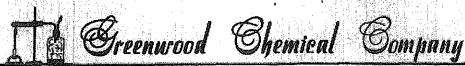
98% Minimum

129°C Minimum

.25% Maximum

White to Cream

The above data are based on tests and experience which Greenwood believes reliable and are supplied for information perposes only. Greenwood makes no warranty concerning this product except that product shall be guaranteed as to its conformity to the above specifications. Greenwood discisions any liability for any demago or injury resulting from the use of this product.





State Highway 690 P. O. Box 26 Greenwood, Virginia 22943

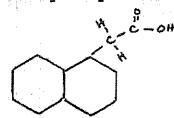
Telephone 703 456-6832

Alpha-NAPHTHALENE ACETIC ACID

EPA REGISTRATION NO. 11546-2

163,61-3 PRODUCT IDENTITY

Our product is Alpha-Naphthalene Acetic Acid



Chemical Abstracts No. 86-87-3

Specifications: NAA

98% Min.

Inerta

2% Max.

Malting Point

129°C Min.

Ash

.25% Max.

Color

White to cream

Form

Crystals

Molecular Weight

186.20

Alcohol Insolubles

0.1% Max.

Moisture

0.5%

| *Pages 300-307 Manufacturing process information may be entitled to confidential treatment* |
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| *Quality control process information may be entitled to confidential treatment* |
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State Highway 690 P. O. Box 26 Greenwood, Virginia 22943

Telephone 703 456-6832

PRODUCT SPECIFIC DATA REPORT

Alpha-NAPHTHALENE ACETIC ACID

EPA REGISTRATION NO. 11546-2

- 163.61-8(1) Color: White to cream crystals
- 163.61-8(2) Odor: None
- 163.61-8(3) Melting Point: 129°C Minimum
- 163.61-8(4) Solubility: Slighly soluble in water. Soluble in toluene, acetone, ether, chloroform.
- 163.61-8(5) Stability: Stable
- 163.61-8(6) Octanol/water partition coefficient: Not Regulred
- 163.61-8(7) Physical State: Solid-Gream to white crystals
- 163.61-8(8) Density of specific gravity: Not Required
- 163.61-8(9) Boiling Point: Not Required
- 163.61-8(10) Vapor pressure: Not Required
- 163.61-8(11) pH: Not Required
- 163.61-8(12) Storage Stability: Stable long shelf life.
- 163.61-8(13) Flammability: None
- 163.61-8(14) Oxidising or Reducing Action: None
- 163.61-8(15) Explosiveness: Non-explosive.
- 163.61-8(16) Misciability: Not Required.
- 163.61-8(17) Viscosity: Not Required.
- 163.61-8(18) Corrosian Characteristics: Non-Corrosive.
- 163.61-8(19) Dielectric breakdown voltage: Not Required.

March 19, 1982

Ar. Mwin C. Johnson Deputy Assistant Administrator for Posticine Programs Registration Division (75-767) Office of Posticide Programs ENVIRONMENTAL PROTECTION ACENCY Washington, D.C. 20460

> 1-NAPHTHALEME ACETIC ACID 1-NAPHTHALENE ACETIC ACID SODIUM SALT

Dear Mr. Johnson:

Attached to this letter is our request for a waiver on requirements for submitting additional data.

On the matter of data already submitted, we have recently set with Union Carbide personnel at Research Triangle, N.C. to discuss the data, which they have submitted inorder to register their formulated products. However, we are unable to reach an egreement with them to share the cost, because they are insisting on our assuming one-half of their expenses. which they estimate at \$250,000 to \$300,000. Such an amount of money would be an impossible burden for a small company. We just cannot come up with even one-half of that amount.

In the meantime, Union Carbide Company has taken edvantage of the law and has decided to become a producer of the basic product, 1-Haphthalene Acetic Apid. They have notified some of the users of MAA that they (Union Carbide) will waive sharing of the cost of obtaining data, if the users (gurchasers) will buy from Union Carbide. Such a situation puts us at Greenwood Chemical at a disadvantage, since we cannot use the law is such a menner. Our position is that for a large company to use the law to their own advantage was not the purpose of the law. The law was not adopted to put small companies out of busines, and make large companies - larger.

It is our deaire and intention to continue as a producer of 1-Naphthalene Acetic Acid, and its acdium salt, and we are asking the EPA to help us.

Clinton C., Signan, President.

Robert Megrall, Chebical Engineer

M/ar

cc: Mr. Robert Taylor Mr. Dan Dickson

Herch 19, 1982

My. Mivin C. Johnson
Deputy Assistant Administrator for Posticide Programs
Registration Division (75-767)
Office of Posticide Programs
ENVIRONMENTAL PROTECTION AGENCY
Machington, D.C. 20406

Dear Mr. Johnson

Reference: VAIVER ON DATA REQUIREMENTS YOU:

1-Eaphthalone Acetic Acid - EPA REG. NO. 11546-2

1-Nephthalone Acotic Acid Sodium Salt - EPA REG. NO. 11546-1

Our company is requesting that additional laboratory work to provide data, as shown in Table A of the "Registration Guidance Package", be waived. Specifically, we request waiver of requirements for data on:

163.81-1 ACUTE ORAL TOXICITY

Data on this subject was submitted by Arnold J. Lehnan in "Report to the Association of Food & Drag Officials" - U.S. <u>Guarterly Bulletin</u>, XV, number 4, page 122. (See microfilm at FDA library.)

163.81-2 ACUTE DERMAL TOXICITY

There is no evidence after thirty years of use in the practical world that MAA or MAASS are absorbed through the skin.

163,61-3 ACUTE INHALATION TOXICITY

Our product is produced as a filter cake which is dried and then ground up. The grinder does not produce fine particles; therefore there is little dust that could be absorbed through need passages. We are having additional work done on the percent of particle below 10 micron size.

163.81-4 PRIMARY EXE IRRITATION

Greenwood Chemical will contract with a suitable testing lab to obtain this data according ja protocols set forth in MA guidelines.

*Commercial/financial information may be entitled to confidential treatment

Mr. Johnson March 19, 1982 Page 2

163.81-5 PRIMARY SKIN IRRITATION

There is no evidence in thirty years of use that exic irritation is a eignificant problem.

NOITAXITIEMSE JANSED 3-18.631

There is no evidence in thirty years of use of sensitization of skin.

To Summariso: l-Haphthalono Acotio Acid and ito codium salt havo boco made for some thirty years, and by this company here since 1969. There has been so reports of adverse reactions in human beings. Our employees are exposed to these products, especially during grinding, drying, and packagoing, and there have been no problems with eye irritation, skin irritation, or dermal sensitiention.

Our company believes in producing chemicals safely and in preventing exposure to potentially hazardous materials. However, we believe there is a practical limit to the excunt of test work on animals that should be done. After all, our actual experience on human beings is most revealing and aignificant. even if set obtained under rigid scientific protocols.

There should be limits to test work on established and long-time produced charleals because of:

- (a) Cost the cost of deing the work which must be added to selling price, thus increasing inflation and, also, the cost of administration, which increases the size of government and the expense.
- (b) Use of Test Facilities there is a limited number of qualified testing inhoratories, and these are needed for new and waknown products. To tie these facilities up testing a provon à longed used product does not mise good sonse.

Finally, these products are produced in relatively minor quantities, pounds por year. Therefore, it is our position that the EPA administration should interpert Sec 3 (2) (A) "with respect to minor uses" in such a way that no unreasonable economic burden is placed on producing osmaniee.

In conclusion, we are acking for a univer of the requirements for call-l data cas l63.81-1 ACUTE ORAL TOLKTITY ... tional data cas

Mr. Johnson March 19, 1982 Page 3

> 163.81-3 163.81-5 163.81-6

ACUTE INHALATION TOLICITY PRIMARY SKIB INDITATION

DERNAL SERVIZATION

We will contract with a testing laboratory to obtain data one

163.61.

PRIMARY BYE IRRITATION

Robert Morrill, Chemical Magineer

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FER 18 1982

sjellen Capin

Greenwood Chemical Company State Mighway 690 P.O. Box 26 Greenwood, VA 22943

Attention: Poper B. Porrill

Centlemens

Subject: 1-Maphthaleneacetic Acid Socion Ealt

EPA Registration Bo. 11546-1 1-Naphthaleneasetic Acid BPA Registration Bo. 11546-2 BBA Reregistration

This asknowledges receipt of jour submission of February 5, 1982, forwarding "FIFRA 3(c)(2)(8) Summary Sheets" for the subject products. The information submitted is acceptable and will be made a part of the records for these products.

Sinceroly,

Pobert J. Taylor Product Manager (25) Pungicide-Berbicide Branch Registration Division (TS-767C)

RD:TATIOR:DCR-27654:WANG-0804A:pjb:Raven:479-2013:02/16/82

FIFTA 5 3 (C) (2) (B) SUMARY SEET

| EPA Registration No.: | 11546 VA1 | |
|--|--|----------|
| Product Name: 1-Na | phthalene Acetic Acid | , |
| Applicant's Nama: Gree | | 5 |
| Registration Standard for | | . |
| Date Registration Standar Date Quidance Package Iss | | . |
| nata entoruca Lackada Tar | August 18, 1981 | • |
| With respect to the requisection 3(c)(2)(B) notice responding in the follows | irament to submit "generic" data imposed by the FIFRA a contained in the referenced Guidance Package, I am ing manner: | • |
| 1. Attached is | a completed "Generic Data Exemption Statement." | |
| cor are not process or Chemicals G | it data in a timely manner to satisfy the following s. If the test procedures I will use deviate from specified in) the Registration Guidelines or the ontained in the Reports of Expert Groups to the roup, OECO Chemicals Testing Programms, I enclose is that I will use: | |
| requirements | red into an agreement with one or more other registra § 3(C)(2)(B)(ii) to satisfy the following data s. The tests, and any required protocols, will be EPA by (name of other registrant). | ries |
| Agreement Wi | completed "Statement of Willingness to Enter Into An ith Other Registrants For Development Of Date" with the following data requirements: | • |
| 5. I request the | at you amend my registration by deleting the following | ng |
| 6. I request vo | olumntary cancellation of the registration of this pro- | îu ta co |
| Dated: 11/02/81 | | 0000 |
| Registrant's Authorized | 1 7 7 7 999 | , // . |
| Representative: | for the file on | 00000 |
| Re-Submitted 2/05/82 | (signature) | 00000 |
| | Robert E. Merrill | 96 08 |
| | (5/245) | |

INTO AN AGREEMENT WITH OTHER REGISTRANTS POR DEVELOPMENT OF DATA

(1) I am duly authorized to represent the following firm(s) who are subject to

| | Name of Pirm | 2PA Company Number * |
|------|---|---|
| | Greenwood Chemical Company | 11 <i>5</i> 46 VA1 |
| | | |
| | | |
| | (This firm or group of firms is referred | to below as "my firm".) |
| . (2 |) My firm is willing to develop and submit Notice, if necessary. However, my firm agreement with one or more other registra share in the cost of developing, the following the state of developing. | rould prefer to enter into an unts to develop jointly, or to |
| | Toxicology data listed in Table A. | • |
| | Ecological Effects listed in Table A | |
| | Residue Chemistry listed in Table A | • |
| (3) |) My firm has offered in writing to enter if offered to be bound by an arbitration dec 3(c) (2) (8) (iii) if agreement on all terms | ision under FIFRA Section could not be reached otherwise. |
| | This offer was made to the following firm | E(S) On the following date(S): |
| | Firm | Date of offer |
| | | |
| | | |
| • | | |
| | | |
| | • | |
| | | |
| | Bowever, none of those firm(s) accepted m | y offer. |
| (4) | My firm requests that EPA not suspend the product(8), if any of the firms named in to submit the data listed in paragraph (2 | paragraph (1) above have agreed |
| | | nform me whether my firm must |
| | Motice. I understand EPA will promptly i submit the data to avoid suspension of it Section 3(c)(2)(B). | s registration(s) under PIFRA |
| | submit the data to avoid suspension of it Section $3(c)(2)(B)$. | |
| | submit the data to avoid suspension of it | |
| | submit the data to avoid suspension of it Section $3(c)(2)(B)$. | Mober Minilani |

NOV 24 1981

Greenwood Chanical Company State Highway 690 P.O. Box 26 Greenwood, VA 22943

Attention: Robert E. Merrill

Gomtlemon:

Subject: 1-Maphtbalene Acetic Acid Sodium Salt EPA Registration He. 11546-1 Maphtbalene Acetic Acid EPA Registration No. 11546-2 WAA Recognitivation Standard

Please note that you are not eligible to use the "Generic Data Exemption Statement" for use in the reregistration of the subject products. Since you are the manufacturer of the technical chemicals, you are responsible for supplying the required data found in Table 1 and 3 of the guidance package. Please complete and return the enclosed "FIVRA 3(c)(2)(3) Summary Shoot" filling in the appropriate black.

Sinceroly,

Robert J. Taylor Product Manager (25) Fungleids-Serbicide Sranch Registration Division (TS-767c)

MO:TAYLOR:DCR-27800:WANG-01038:hjc:Baven:479-2013:11/20/81

State Highway 590 P. C. Box 26 Greenwood, Virginis 22943

Telephone 703 456-6832

My

November 6, 1981

Mr. Dan Dickson

Product Manager - NAPHTHALENE ACETIC ACID PRODUCTS

REGISTRATION DIVISION (75-767)
Office Of Pesticide Programs

ENVIRONMENTAL PROTECTION AGENCY

Washington, D.C. 20460

Dear Sir:

Enclosed are re-registration forms for our two technical products:

11546-1 NAPHTHALENE ACETIC ACID SODIUM SALT

11546-2 NAPHTHALENE ACETIC ACID

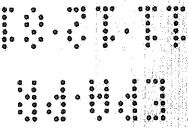
The next batch of data will be sent according to your schedule.

Please note that these products are classified in the minor-use category.

Very truly yours

Robert E. Merrill Chemical Engineer

Enclosures: 6 (2 sets of 3 each)



FIFRA § 3(C)(2)(B) SUMMARY SHEET

| Registration Data Registr Data Guidano With respect section 3(c) | |
|--|--|
| 1. XX | Attached is a completed "Generic Data Exemption Statement." $III-I$ |
| 2. | I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use: |
| 3. | I have entered into an agreement with one or more other registrants under FIFRA § 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by (name of other registrant). |
| | I enclose a completed "Statement of Willingness to Enter Into An Agreement With Other Registrants For Development Of Data" with respect to the following data requirements: |
| 5. | I request that you amend my registration by deleting the following uses: |
| 6. | I request voluntary cancellation of the registration of this product. |
| Dated: | /02/81 |
| Registrant's Representat | /// b.g gas u /~~// bag u /~~// ba |

GENEFIC DATA EXEMPTION STATEMENT

| EPA Product Registration Number: 11546-2 |
|--|
| Registrant's Name: Greenwood Chemical Company |
| As an authorized representative of the registrant of the product identified above, I hereby cartify that: |
| (1) I have read and am familiar with the terms of a Notice in a Guidance Package from EPA dated Reverse concerning a requirement for submission of generic data on the active ingredient length Action Action Action (2) (2) (3). |
| (2) My firm requests that EPA not suspend the registration of our product, despite our lack of intent to submit the data in question, on the grounds that the product is an end see product and it donesans the active ingredient solely as the result of the encorpolation into the product (during formulation or packeting) of a manufacturing up product which contains that serve ingredient, which is registered under FIFRA Section 3, and which is purchased by us from another producer. |
| (3) An accurate confidential formula statement for the above-identified product, is attached to this statement. That formula statement indicates, by company hame, registration number, and product pame, the source of the active inpredient in my firmula are duct. My file all apply for an amendment to the source of the active ingredient in our product. |
| (4) I understand, and agree on behalf of my firm, that if at any time any portion of this Statement is no longer true, or if my firm fails to comply with the undertaking made in this statement, my firm's product's registration may be suspended in accordance with PIPRA Section 3(c)(2)(B). |
| Dated: 11/02/81 |
| Registrant's Authorized Representative: (Signature) |
| (2yed) |
| President of the Company on November 2, 19-1. |
| TOTAL METANOMIA TO THE PROPERTY OF CONTRACT TO A CONTRACT TO THE CONTRACT TO T |

State Highway 690 P. O. Box 26 Greenwood, Virginia 22943

Telephone 703 456-6832

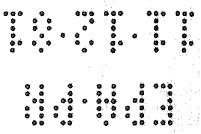
November 2, 1981

(5) We firm requests that EPA re-register our product because experience has shown that its manufacture and use are safe in respect to living organisms and the environment.

We also dite the classification of these products in the "minor-was" category (page 12 - Pesticide Registration Standard) which means that many data requirements are waived, and the statement "the Agency has concluded that it should continue the registration of this chemical" (page 13 - Pesticide Registration Standard).

Finally, our product is sold only to re-formulators, or compounders. We do not sell directly to consumers.

11/2/81





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

011546
GREENWOOD CHEMICAL COMPANY
STATE HIGHWAY 690
GREENWOOD VA
22943

11546,2

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

AUG 181981

SUBJECT: Initiation of Reregistration Process for Pesticide

Products Containing Naphthaleneacetic Acid

as the Single Active Ingredient

Dear Registrant:

In accordance with the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, (FIFRA), the Office of Pesticide Programs, EPA, has begun the reregistration process for pesticide products containing the subject ingredient. Significant changes to the statute were made in 1972, 1975 and 1978; thus, current requirements may be substantially different from those in effect at the time your product(s) was registered. The first phase of reregistration requires that you (1) make a commitment to the Agency regarding data development and (2) subsequently submit revised product labeling and associated information.

This mailing contains the Registration Standard, a Guidance Package for preparation of submissions, as well as a listing of your affected products (Attachment A) and a separate list of registrants with products containing this active ingredient (Attachment B). The latter list is for the purpose of cooperative data development. Together they should provide you with all the information you need to meet the necessary requirements and to allow you to continue your registration(s) in effect.

The Registration Standard sets out the Agency's evaluation of all available data pertaining to the subject chemical and its registered uses, EPA's assessment of the hazards associated with uses of the pesticide, as best they can be assessed with the data currently available, and its rationale for the regulatory actions being taken at this time.

The Guidance Package, together with the first and second chapters of the Standard contain instructions describing what you must do to bring your product(s) into compliance with the

BREENHOOD CHEMITAL COMPANY BYATE HIGHMAY 670 BREENWOOD YA 011546

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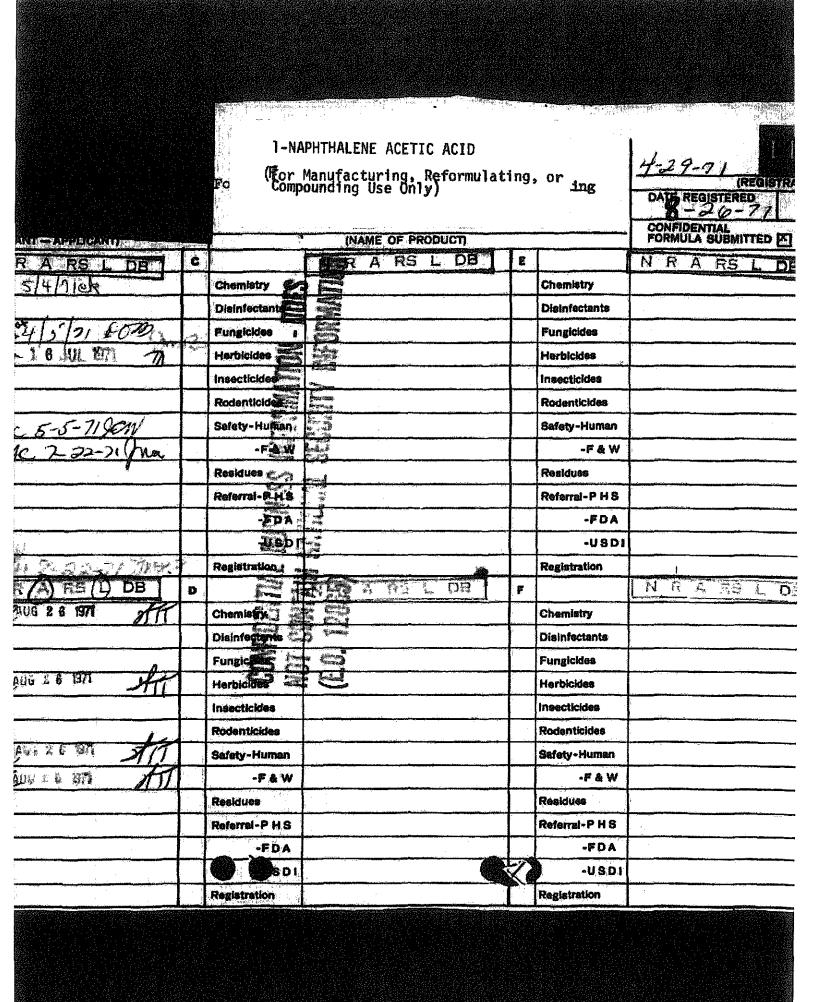
57442

511546×00001

1 - MAPHTHALEMEACETIC ACID BODIUM BALT

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I-NAPPHALENE ACETE ACEG



State Highway 690
P. O. Box 26
Greenwood, Virginia 22943

Telephone 703 456-6832

September 26, 1980

Mr. Dan Dickson Registration Division TS-767 UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street 3.W. Washington. DC 20460

Dear Mr. Dickson:

On April 10, 1980 you sent me copies of the registration and approved lables for 1- Naphthalene Acetic Acid and for 1-Naphthalene Acetic Acid sodium salt. At the time I felt this material would be more than enough to satisfy our customer and their government, but as you can see from the enclosed letter, they need these approvals on EPA letterhead. If you can send me copies of the approved registration and label on your EPA letterhead, I would greatly appreciate it. It may help to satisfy the Taiwan government.

I am enclosing a copy of our approvals from the USDA and a copy of the letter from our customer. I am also enclosing copies of our approved labels just in case you may need them.

Please send this information to me and I will forward it to our customer in Taiwan. Your speedy response to this matter is very much in need.

Cordially yours,

Thankon Roberta

Shannon Roberts

Enclosure: 5

REGISTRATION NO. U. S. DEPARTMENT OF AGRICULTURE 11546-2 AGRICULTURAL RESEARCH SERVICE DATE OF ISSUANCE PESTICIDES REGULATION DIVISION August 26. 1971 NAME OF ECONOMIC POISON NOTICE OF REGISTRATION UNDER THE FEDERAL 1-NAPHTHALENE ACETIC ACID (For INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT Manufacturing, Reformulating, or Compounding Use Only) NAME AND ADDRESS OF REGISTRANT Greenwood Chemical Company Greenwood, Virginia 22943 NOTE: Changes in labeling or formula differing in substance from that accepted in connection with this registration must be submitted and accepted by the Pesticides Regulation Division prior to use of the label in interstate commerce. In any correspondence on Product always refer to the above registration number. the basis of the information furnished by the registrant, the above named economic poison is hereby registered under tion 4 of the Federal Insecticide, Fungicide, and Rodenticide Act. A copy of the labeling accepted in connection with this registration is returned herewith. Registration is in no way to be construed as an endorsement or approval of this product by this Department. In order to protect the public, the Secretary, on his own motion, may at any time cancel the registration of an economic poison in accordance with Section 4 (c) of the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by a trademark held by others. The following paragraphs are applicable only when checked: To expedite registration, this notice is being issued on the basis of the draft submitted with the application. Certain defects, given below, have been noted. These corrections must be incorporated when the printed labeling is prepared. Five copies of the printed labeling must be submitted to complete the file on this product. The registration for this product is being issued with the understanding that certain defects in the labeling which are noted below will be corrected as soon as possible. Objection is not raised to the use of the present labeling for a reasonable period of time while fully corrected labeling is being prepared. Five copies of the corrected labeling must be submitted. HTToma: ie James M. Rea Attachment is applicable. Head, Registration Review (Herbicides) SIGNATURE MEACA-MEGNAMAMAMAGNASIONA PESTICIDES REGULATION DIVISION CENTING STOCK OF PR FORM 9 225, MAR. 1962, WILL BE USED UNTIL CHIAUSTED 9-225 FORM OCT. 1964

1-NAPHTHALENE ACETIC ACID

| ACTIVE INGREDIENT: 1-NAPHTHALENE ACETIC ACID | • |
|---|--------|
| TOTAL 3 | 100.0% |
| usda reg. no. 11546-2 net weight | · |
| CAUTION: KEEP OUT OF REACH OF CHILDREN | 4. |

MAY CAUSE IRRITATION OF NOSE, THROAT AND MAY BE HARMFUL IF INHALED OR SWALLOWED. DO NOT BREATHE DUST. USE WITH ADEQUATE VENTILATION. AVOID CONTACT WITH EYES, SKIN OR CLOTHING. WASH THOROUGHLY AFTER HANDLING. KEEP AWAY FROM FEED OR FOOD PRODUCTS. DO NOT REUSE EMPTY CONTAINER. DESTROY EMPTY CONTAINER BY PERFORATING OR CRUSHING AND BURYING IN A SAFE PLACE.

DIRECTIONS FOR USE:

Manufactured By:
GREENWOOD CHEMICAL COMPANYS
GREENWOOD, VIRGINIA 22943

ACCEPTED

ANG 26 1971

under the federal heacticide act fungicide and somethicide act for economic potton registered nurs no. 1242 Eublect to attached comments.

Rehab Group Inc. Arlington, Va. AOSSS qiS OOBT-152 (EOT)

8Tet - 63M117

328

Posticióus inforcement Division

O DEC 1971

Sichmond and Timburna Actorna n at Lar Actorion at Lar 240 Court Square Charlogges 112 Virginia 2201

Contlance:

Subject: I. b. No. 100656 - 1-NAPERRALANE ACCRIC ACTO

Greenwood Camical Company Greenwood, Virginia

Reference is wast to your latter of Sevenhar 17, 1971, with enclosures,

is note that the product is now registered for Greenwood Charles Cornery under registration number 11546-2. In selfcion, we further note that your client is improving internal plant controls to make every employed aware of the importance of full compliance with the Act.

Inclosed are the existed copies of the accepted label and Fe Form 4-225 for the products accepted under Eas. Sec. 11546-1 and 11546-1.

The Agency has decided to held this care open for further consideration.

/s/ A. E. Conroy. II

A, A. Contoy Li Director

Enclosures

Cor Lag. No. 11546-2 Supervisory Imapector Tennis/Inspector Project Code P-5

DAILE: Genters: caj 12-17-71

Greenwood Chemical Company Greenwood, Virginia 22943 By JUL 197

Gentlemen:

Subject : ALPHA NAPHTHALENE ACETIC ACID For Manufacturing,

Reformulating, or Compounding Use Only

File Symbol 11546-E

Your application of April 23, 1971

The product referred to above will be acceptable for registration under the Federal Insecticide, Fungicide, and Rodenticide Act; provided, finished labeling is submitted incorporating the following revisions.

- 1. Correct the chemical to read "1-Naphthaleneacetic acid."
- 2. It is assumed that the net contents will be declared on the label or on the container.

"USDA Reg. No. 11546-2" is being reserved for this product. This must appear on the finished label. The "Notice of Registration," will be issued when five copies of the acceptable finished (printed) labeling are submitted. Finished labeling is that which will be attached to or accompany the product. Refer to the attached "A-86 enclosure."

To expedite handling, please return the enclosed duplicate copy of this letter along with your finished labeling.

This letter does not constitute registration and the product may not be lawfully marketed in interstate commerce until it is registered.

Sincerely.

James M. Rea Hing

Head,

Registration Review (Herbicides)

2 Enclosures

A-86

Dupl. Letter

EPA:PR:JMRea:je 7-23-71

REXMANDER

| | FORM APPROVED: BUDGET BUREAU NO. 40-R1746 | | |
|---|--|--|--|
| U.S. DEPARTMENT OF AGRICULTURE | 1. DATE OF APPLICATION APT 11 23, 1971 2. NAME OF ECONOMIC POISON (Must be same product name as on label-do not list active ingradients) | | |
| Agricultural research service - Pesticides regulation division | | | |
| Washington, D. C. 20280 | | | |
| APPLICATION FOR NEW REGISTRATION OF ECONOMIC POISONS | | | |
| (Under the Federal Insecticide, Fungicide, and Rodenticide Act) | | | |
| | | | |
| IMPORTANT: READ INSTRUCTIONS ON REVERSE | Alpha Naphthalene Acetic Acid | | |
| 3. TYPE OF PESTICIDE (Check each applicable item for combination products) INSECTICIDE PUNGICIDE MERBICIDE | ОТНЕК (Specify) | | |
| | Plant Regulator | | |
| RODENTICIDE GERMICIDE-DISINFECTANT | <u> </u> | | |
| 4. NAME & MAILING ADDRESS OF FIRM TO WHOM REGISTRATION IS TO BE (Include Zip Code) | isued s. Is the registrant shown in Item 4 the Manufacturer? | | |
| Greenwood Chemical Company | YES KN NO [] | | |
| Greenwood, Virginia 22943 | | | |
| Cathada talganan ass to | (If "No", see instruction 5 on | | |
| | reverse) | | |
| | | | |
| 6. TYPE OF FORMULATION | OTHER (Specify) | | |
| DUST WETTABLE POWDER PRESGURIZED PRODUCT | | | |
| GRANULAR EMULSIFIABLE LIQUID BAIT | | | |
| 7, TYPE OF CONTAINER OTHER (Specify) | 8. NET CONTENTS OR CONTAINER SIZES | | |
| METAL GLARS | • | | |
| PLANTIC PAPER Fibre carton | 25, 50, 100, 150 lbs. | | |
| INER IN WHICH LABEL IS AFFIXED TO PRODUCT | OTHER (Specify) | | |
| LITHOGRAPHED PAPER, GLUEDEN STENCILE | ™ | | |
| 19, place where directions for use appear | | | |
| on label 🔀 in printed matter accompanyin | G PRODUCT | | |
| 11. Data Bubmitted with this application (Identify and Submit in triplicate) | | | |
| EFFICACY DATA TOXICOLOGY DATA REGIDU | E DATA PETITION FOR TOLERANCE | | |
| other (Specify): | | | |
| | | | |
| None, as this is an established product | | | |
| i2. Any additional pertinent information (Do not enter confidential formula h | ere-see item 13, below) | | |
| Precautionary statement - Assay - Label to read | s Day manifacturing material | | |
| Frecaucionary statement - Assay - Laber to read | or compounding use only. | | |
| | or compounding use only. | | |
| | | | |
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| | | | |
| | e e e e e e e e e e e e e e e e e e e | | |
| 13. The following MUST be subbitted with application | 17. RECEIVED BY USDA - PESTICIDES REGULATION | | |
| 6 Five (5) capies of proposed labeling, including all printed or graphic matter which | DIVISION, WASHINGTON, D. C. | | |
| may accompany the sale of this product. Capter must be clearly legible and identical, | | | |
| Five (5) copies of the complete formula, showing the precise name and percentage | 1/6-1/1/ | | |
| of each active and each inest ingredient. (This information is treated confidentially.) | | | |
| | | | |
| 14. Signature of Authorized Firm Representative | | | |
| Clause A Hustraled | 9 989 98 9 989 | | |
| O-11-17-14-17-1 | 9 40 4 6 6 6 | | |
| 3. TITLE 16. DATE SIGNED | 9 | | |
| President April 23, 197 | 1 | | |
| PR FORM 9-199 EXISTING STOCK OF PRFORM 9-199 (JULY 1966 | 3) | | |
| May 1969 WILL BE USED UNTIL EXMAUSTED | 10.01 | | |

ALPHA NAPHTHALENE ACETIC ACID

ACTIVE INGREDIENT: Alpha Naphthalene Acetic Acid

44.5%

INERT INGREDIENTS:

1.5%

TOTAL

1:41.07.

CAUTION: (1) KEEP OUT OF THE REACH OF CHILDREN. '-'

MAY CAUSE IRRITATION OF NOSE, THROAT AND MAY BE HARMFUL IF INHALED OR SWALLOWED. DO NOT BREATHE DUST. US& WITH ADEQUATE VENTILATION. AVOID CONTACT WITH EYES, SKIN, OR CLOTHING. WASH THOROUGHLY AFTER HANDLING. KEEP AWAY FROM FEED OR FOOD PRODUCTS. DO NOT REUSE EMPTY CONTAINER. DESTROY EMPTY CONTAINER BY PERFORATING OR CRUSHING AND BURYING IN A SAFE PLACE.

DIRECTIONS FOR USE: FOR MANUFACTURING, REFORMULATING OR COMPOUNDING USE ONLY.

MANUFACTURED BY:

GREENWOOD CHEMICAL COMPANY GREENWOD, VIRGINIA 22943

- (1) to be 18 point type
- (2) to be 14 point type